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ROYAL COMMISSION OF INQUIRY INTO CERTAIN  
DEATHS AT THE HOSPITAL FOR SICK CHILDREN AND  
RELATED MATTERS.

Hearing held  
8th floor  
180 Dundas Street West  
Toronto, Ontario

The Honourable Mr. Justice S.G.M. Grange

X Commissioner

P.S.A. Lamek, Q.C.

Counsel

E.A. Cronk

Associate Counsel

Thomas Millar

Administrator

Transcript of evidence  
for  
November 30, 1983

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1 ROYAL COMMISSION OF INQUIRY INTO CERTAIN  
2 DEATHS AT THE HOSPITAL FOR SICK CHILDREN  
3 AND RELATED MATTERS.

4 Hearing held on the 8th Floor,  
5 180 Dundas Street West, Toronto,  
6 Ontario, on Wednesday, the 30th  
7 day of November, 1983.

8 THE HONOURABLE MR. JUSTICE S.G.M. GRANGE - Commissioner  
9 THOMAS MILLAR - Administrator  
10 MURRAY R. ELLIOT - Registrar

11 - - - - -  
12 APPEARANCES:

13 P.S.A. LAMEK, Q.C. Commission Counsel  
14 E. CRONK )  
15 D. HUNT ) Counsel for the Attorney  
16 L. CECCHETTO ) General and Solicitor General  
17 M. THOMSON ) of Ontario (Crown Attorneys  
18 R. BATTY ) and Coroner's Office)  
19 D. YOUNG Counsel for The Hospital for  
20 W.N. ORTVED Sick Children  
21 B. SYMES Counsel for the Registered  
22 Nurses' Association of Ontario  
23 and 35 Registered Nurses at  
24 The Hospital for Sick Children

25 (Cont'd)





1

APPEARANCES: (Continued)

2

D. BROWN

Counsel for Susan Nelles -  
Nurse

3

G.R. STRATHY)  
E. FORSTER )

Counsel for Phyllis Trayner -  
Nurse

5

J.A. OLAH

Counsel for Janet Brownless -  
R.N.A.

6

N. GOODMAN

Counsel for Mrs. M. Christie -  
R.N.A.

7

S. LABOW

Counsel for Mr. & Mrs. Gosselin,  
Mr. & Mrs. Gionas, Mr. & Mrs.  
Inwood, Mr. & Mrs. Turner, Mr. &  
Mrs. Lutes, and Mr. & Mrs.  
Murphy (parents of deceased  
children)

10

F.J. SHANAHAN

Counsel for Mr. & Mrs. Dominic  
Lombardo (parents of deceased  
child Stephanie Lombardo); and  
Heather Dawson (mother of  
deceased child Amber Dawson)

13

W.W. TOBIAS

Counsel for Mr. & Mrs. Hines  
(parents of deceased child  
Jordan Hines)

14

J. SHINEHOFT

Counsel of Lorie Pacsai and  
Kevin Garnet (parents of  
deceased child Kevin Pacsai)

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A/BM/ak

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---Upon commencing at 10:00 a.m.

3

DR. RALPH KAUFFMAN, Resumed

4

THE COMMISSIONER: Yes, Miss Cronk.

5

MS. CRONK: Good morning, sir.

6

DIRECT EXAMINATION BY MS. CRONK: (Continued)

7

Q. Doctor, yesterday you will

8

recall that we discussed, amongst other matters, the likelihood in your view of a medication error having occurred in the cases of Stephanie Lombardo, Jesse Belanger and Jordan Hines and you referred us in the course of your response to those questions to a recent abstract that had been published you said in July of this year having to do with myocardial clearance of digoxin. You have now provided a copy of that abstract to me. I would ask you to identify it as the abstract that you were referring to yesterday.

17

A. Yes, this is the one.

18

Q. As I understand it, Doctor,

19

there are a number of matters that you wish to draw to our attention from that abstract.

21

A. Yes, there are.

22

THE COMMISSIONER: Is this an abstract from textbook.

23

THE WITNESS: No, I should have

24

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identified this at the top before it was copied and  
I didn't do that. This is an abstract from the  
proceedings of the International Society for Clinical  
Pharmacology which met in Washington, D.C. in July of  
1983 and this paper was presented orally at that  
meeting and this was an abstract of the paper which  
was published in the proceedings of that meeting.

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THE COMMISSIONER: Yes, thank you.

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MS. CRONK: Q. Doctor, could you  
outline for us if you will please the matters that  
you feel are of relevance?

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A. Yesterday when I alluded to  
this paper I was doing so by memory having not looked  
at it for several months. My memory didn't serve me  
as well as it should have and, so, I was in error in  
some of the details that I presented to you and I  
would like to correct that now and go through the  
abstract with you and give you the details because I  
think this is important information in this context.

Q. Please do, Doctor.

A. This study was carried out on





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3 45 adult patients. I don't remember specifically  
4 yesterday whether I said they were adults or children  
5 but these were on 45 adult patients who were under-  
6 going open heart surgery and had been on chronic  
7 digoxin therapy for at least six months or longer at  
8 the time of their surgery. So, they were on chronic  
digoxin therapy.

9 At the time of surgery serum digoxin  
10 was measured in their serum as well as in samples  
11 taken from atrial myocardium or papillary muscle  
12 ventricular myocardium and the time at which the  
13 digoxin sample was taken varied with each patient of  
14 after their last dose; in other words, the time from  
15 the last dose of digoxin to the time of the sampling  
varied with each patient from anywhere from one day  
16 up to 20 days.

17 Getting these samples then and pulling  
18 this data the authors attempted to estimate the half  
19 life with which digoxin in this particular group of  
patients disappeared from the serum and from the  
20 heart. This is the first information that I am aware  
21 of where this specific issue has been addressed  
22 experimentally in human beings.

23 The decline in serum digoxin levels  
had a beta half life in this particular group of  
24

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patients of 48 hours. There is a variation but this  
was the average. The decline in the heart muscle  
levels were essentially the same, the half life was  
essentially the same for both atrial and ventricular  
myocardium but it was longer than the serum.

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The decline in myocardium during the  
alpha phase or what appeared to be an alpha phase,  
the short half life phase, was 7 to 12 hours and the  
slow elimination or the so-called beta phase was  
three and a half days for papillary muscle and four  
and a half days for right atrial appendage but this  
was not statistically significant.

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16

In some of the patients, and I don't  
know how many, but in some of the patients who had  
received their last digoxin dose 20 days prior to  
surgery digoxin was still present and detectable in  
the tissues up to 20 days.

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Q. Thank you, Doctor. May I, in  
light of the information afforded by this abstract,  
Doctor, take you now back for a moment to the case  
first of Stephanie Lombardo. You will recall in that  
case that the child was admitted to the Hospital on  
December 13th and died December 23rd and that there  
were assay results both on RIA, HPLC and RIA and on  
mass spectrometry from the Centre of Forensic Sciences





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showing digoxin in a variety of tissues in that child.

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Given the information provided by this abstract, would you expect to see first traces of digoxin in tissue samples from that child if a therapeutic or maintenance dose of digoxin was given to the child at any point during those 10 days?

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A. There are two caveats that

we have to look at; one is that the study that I just alluded to was done in middle age adults. So, I don't know whether they would be different than infants; the second is that they were on chronic digoxin therapy. In this case we are postulating a single dose of a maintenance dose by error. We know that the concentrations in the tissues are much higher with chronic therapy than with the single dose and the total amount of digoxin in the patients in the study would be considerably greater per body weight than the amount of digoxin in the total body after a single maintenance dose. So, we have to take that into consideration.

But accepting that, I think if we are

willing to extrapolate the data from this study to the situation of Lombardo, I think I would say it would be possible following a single dose some time during that 10 days to still be able to detect





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2

3 digoxin in myocardial tissue within that 10 day  
4 period. It is hard for me to assign a probability  
value to it but I certainly think it would be possible.

5

6 Q. And that I take it, Doctor,  
7 would equally be the case, if not more so, were it  
a loading dose that were given to the child in error  
as opposed to a maintenance dose.

8

9 A. Well, half of the usual loading  
10 dose, which would be the situation with a single  
11 error, would be approximately twice a maintenance  
12 dose received error. So, he would expect to be able  
13 to detect the digoxin in tissues a little bit longer  
14 simply because there was more digoxin there to begin  
with.

15

16 Q. I understand. Doctor, having  
17 regard to the specific levels of concentrations of  
18 digoxin which were found in Stephanie Lombardo, you  
19 will recall that you told us yesterday that in your  
20 view, as I understood it, they were both high and,  
21 secondly, that they were consistent in that they were  
22 in a variety of different tissue specimens from her  
23 body. The levels in the heart you will recall were  
24 within the range of 487 in the left ventricle to  
25 667 in the septum of the heart and in chest fluid  
it was 225 nanograms.





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Given the actual concentrations that were found in the child and the number of tissues in which concentrations of digoxin were found, would you consider it likely in your view that those concentrations would be found in this child if a therapeutic or loading dose were given at any time within the 10 days prior to her death?

A. We have to consider the

problem of interpreting numbers from exhumed tissue but if we would accept those numbers of being somewhere in the ball park of what the concentration was at the time of death, then I think it would be quite unlikely that it would be due to medication error 5 to 10 days earlier. The problem is the interpretation of the exhumed tissue concentrations.

Q. Does the abstract, Doctor,

that you provided to us give any indication as to the actual concentrations that were found in the myocardial tissues, be it the one or the 20 days that were sampled. Do we know how much was found?

A. Well, the average concentration

that they mentioned according to my notes from the paper, from hearing it, their actual concentration - these are averages - the average concentration went from around 300 nanograms per gram down to approximately





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3.5 nanograms per gram over 20 days. So that although  
they could detect it by 20 days the concentrations  
were very, very low.

5

Q. All right.

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THE COMMISSIONER: Am I to read this  
that 20 days is the last or is it the last day tested?  
Do they test for 21 or 22, do we know?

9

THE WITNESS: No, that's the longest  
interval between the last dose and surgery.

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THE COMMISSIONER: That is not quite  
what they say, unfortunately. "Measureable levels of  
digoxin were still present on both tissues 20 days  
after stopping treatment." They don't say that they  
were not detectable 21 days after. But I take it  
that is what they mean, is it?

THE WITNESS: But the method of  
the study was that the longest time they measured it  
was 20 days. They don't know if it was there longer  
because they didn't measure it.

THE COMMISSIONER: That's right.

THE WITNESS: They didn't have any  
patients who had not received a dose for more than  
20 days before they had their surgery.

THE COMMISSIONER: But measureable  
levels of digoxin, they don't say how low they were.





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THE WITNESS: Well, from my notes from hearing it - you see, many details aren't in the abstract.

5

THE COMMISSIONER: Yes.

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THE WITNESS: From my notes that I took when I heard the paper presented I have a note that the average concentration declined from 300 nanograms per gram to an average of 3.5 nanograms per gram over these 20 days.

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You have to remember that each patient represented one sample, and so they pooled the data from the 45 patients and there are some theoretical problems with that but it is really the only way you can address this problem in patients.

6

Q. They found then, doctor, after 20 days I take it on average a concentration that would be considered to be of the upper range of the therapeutic level were it achieved during life, for example?

10

A. I am sorry?

11

THE COMMISSIONER: And if it were in serum.

12

MS. CRONK: Q. And if it were in serum, 3.5, the highest was 3.5 that they found after 20 days?

15

A. The average.

16

Q. The average, right.

17

A. I don't know the range, that wasn't provided.

18

Q. Thank you, doctor.

19

Doctor, could we turn then similarly to the case of Jesse Belanger for a moment. You will recall that this child from the time of his admission to the Hospital to the time of his death was hospitalized for approximately 35 days. Again given the information

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B2                   2 that is available to you from the abstract, and having  
3                    regard to the concentrations that were found in this  
4                    child, is it possible in your view that traces of  
5                    digoxin could be found in tissues, and remember again  
6                    that they are exhumed tissues, from his body if a  
7                    therapeutic or loading dose of digoxin had been  
8                    administered to him in error at any time during that  
9                    25-day period?

10                   9                   A.        I suppose it is possible, but  
11                   10                  considering the dose that he would have received under  
12                   11                  those conditions I think it is highly unlikely that it  
13                   12                  would be detected as long as 35 days.

14                   13                  Q.        Doctor, just to refresh your  
15                   14                  memory on that as well, you will recall that with  
16                   15                  Jesse Belanger the actual concentrations found, one  
17                   16                  was assayed again both by RIA, HPLC/RIA and as well  
18                   17                  mass spectrometry, and in the liver by those methods  
19                   18                  a concentration of 253 nanograms per gram was found;  
20                   19                  and in a sample of skeletal muscle a level of 43 nano-  
21                   20                  grams per gram was found.

22                   21                  Having regard to the actual concen-  
23                   22                  trations, is it your view that it is likely that those  
24                   23                  levels could be found if one therapeutic or loading  
25                   24                  dose had been administered at any time during the 35  
                      25                  days?





Kauffman  
dr.ex. (Cronk)

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B3

2 A. Again with the problem of  
3 interpreting the concentrations because of the nature  
4 of the sample; if we accept those numbers as being  
5 somewhere in that general range, then I think it is  
6 even more unlikely that those kinds of levels would  
7 have been detected for a prolonged time after a dosing  
error.

8

9 Q. Doctor, I take it as well  
10 though as Dr. MacLeod suggested in his evidence, based  
11 on this abstract it is certainly possible that some  
tracings of digoxin might be found in tissues?

12

13 A. Yes, I think that is possible  
14 considering -- well, if you have a sensitive enough  
assay and if the initial concentrations were high  
15 enough to leave a trace that long afterwards, a  
detectable trace. I have to say, yes, I think it is  
16 possible, looking at the entire picture here I think it  
17 is somewhat improbable but I think it is possible.

18

19 Q. Doctor, then may we turn to the  
case of Jordan Hines. There is a shorter time interval  
20 still in his case. You will recall that it is  
approximately, I believe I have this correctly, two  
21 days between the time of his admission for something  
under 48 hours and the time of his death. Again in  
22 his case we are dealing both with fixed and exhumed  
23

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B4

2 specimens. The levels in the fixed heart tissue  
3 range between 52 nanograms per gram in the left  
4 ventricle, and 89 nanograms per gram in the septum;  
5 digoxin was as well found in exhumed tissues from the  
6 right thigh muscle 56 nanograms per gram. Assuming,  
7 doctor, that one therapeutic or one loading dose of  
8 digoxin was in error administered to that child during  
9 the two-day period of his hospitalization, at any  
10 point over the two days, would you consider it possible  
11 to find those concentrations of digoxin in his  
tissue specimens after death?

12 A. Yes, I think it would be  
possible.

13 Q. And are you, doctor, able to  
14 express in this case any opinion as to the likelihood  
15 of concentrations of that kind being found, if for  
16 example, a therapeutic or loading dose was given  
17 shortly after his admission to the Hospital?

18 A. Well again if you can accept  
19 the fixed tissues as being the minimum that it could  
20 have been, and you estimate what concentration might  
21 be produced, what maximum concentration might be  
22 produced under those conditions, I think it is possible,  
23 and I think it is difficult to assign a probability to  
24 that. I think that it is somewhat unlikely that it

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B5

2 would have been given as long as 48 hours, but I think  
3 that it is -- the probability of it being given that  
4 long and not being given that long I would say is  
5 essentially equal based on this kind of information  
6 that I have just presented to you.

7 Q. And given as well I take it,  
8 doctor, the actual length of time involved, that is  
9 two days?

10 A. Yes.

11 Q. Thank you, doctor.

12 Mr. Commissioner, before I continue,  
13 Mr. Brown indicated to me this morning that he wished  
14 to address some remarks to you.

15 THE COMMISSIONER: Yes, Mr. Brown.

16 MR. BROWN: Mr. Commissioner, on  
17 occasions before you have suggested to me perhaps this  
18 is not the proper place to address matters which arise  
19 in the media.

20 Yesterday, however, the expurgated  
21 version of the Atlanta Report was released and was made  
22 an exhibit in this Inquiry. Numerous reports appeared  
23 in the press regarding that report, and in particular  
24 a report appeared on Global Television and there was a  
25 picture of a portion of a page of the report of which  
part of the report had been blacked out. I did not





1  
2 B6 personally see the television program on Global,  
3 although I was informed of its contents, and I believe  
4 a comment was made on that portion of the report that  
5 was blacked out. The comment was made suggesting that  
6 the blacked-out portion referred to Nurse Susan Nelles.

7 I have reviewed the expurgated  
8 version of the Atlanta Report and I have reviewed the  
9 unexpurgated version of the Atlanta Report and from  
my review --

10 THE COMMISSIONER: Wait.

11 MR. BROWN: I will be careful.

12 THE COMMISSIONER: Yes. All right.

13 MR. BROWN: From my review I have  
14 been able to ascertain that those portions of the  
15 Atlanta Report which were blacked out did not refer  
directly or indirectly to Nurse Susan Nelles.

16 It is difficult in a Commission of  
17 this nature to put in evidence piecemeal, although I  
18 think there was agreement previously that the Atlanta  
19 Report would be put in only at the proper time.

20 However, in view of the difficulty  
21 in interpreting any information which may be blacked  
22 out, I take great offence to the suggestion that was  
23 made on Global Television; I take offence to any  
speculation which is made by members of the media; and

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B7

2 I further take offence to speculation which is wrong.

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THE COMMISSIONER: Yes. Well they couldn't conceivably have known what was in the blacked-out portion unless they obtained a copy of the unexpurgated report, so they could not have known at all and so therefore it had to be speculation.

MR. BROWN: The blacked-out copy, Mr. Commissioner, is readily subject to analysis and one can readily determine what has been blacked out. That has happened on previous occasions when particular Minutes of meetings were put in. I think the Minutes of the September 13th meeting, and I believe that happened again on this occasion.

THE COMMISSIONER: I had no idea you could do this sort of thing, can you?

MR. BROWN: I believe the media are quite adept and I concede that may well be their job to try and glean any bit of information they possibly can.

THE COMMISSIONER: Well what do you propose, what remedy are you proposing, or are you merely announcing your discontent?

MR. BROWN: Well I am merely announcing my grave discontent over this matter.

THE COMMISSIONER: Yes.





Kauffman  
dr.ex. (Cronk)

B8

1  
2 MR. BROWN: And perhaps as a remedy  
3 there is a practical solution. In future if documents  
4 are going to go in, and part of documents are going  
5 to be expurgated, the safer procedure perhaps to  
6 avoid incorrect speculation would be simply to white  
7 out or physically excise those portions of the document.  
8 It would make it that much more difficult for the  
9 media and would prevent speculation which is completely  
incorrect and unfounded.

10

MS. CRONK: Well, Mr. Commissioner,  
11 I cannot comment on what was or was not said or  
12 implied directly or indirectly last evening because I  
13 did not see the program, nor until just this moment was  
14 I informed about it.

15

I can say on behalf of both Commission  
16 Counsel, Mr. Lamek and myself, that if it was possible  
17 by process of deduction or clairvoyance to understand  
18 what was beneath the blacked-out parts of the report  
19 and if this has caused difficulty for Mr. Brown we  
20 regret that. I don't think I need to go into the  
21 difficulties of doing that, but I can assure Mr. Brown  
22 that I certainly couldn't and we have undertaken  
23 whatever efforts we could.

24

THE COMMISSIONER: Can it be cut out?

25

MS. CRONK: We certainly can, and





1

B9 2 indeed if the situation arises in the future we will  
3 be glad as we did yesterday to consult with Mr. Brown  
4 in advance as to the most appropriate method to achieve  
5 that.

6 THE COMMISSIONER: Mr. Young had  
7 better worry about this, because if the media teaches  
8 the trick to some of the other counsel that police  
9 report is being done the same way so you may be in  
10 trouble.

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Well, I agree. It could only have been speculation. For what it is worth I would just as soon people didn't speculate. We have a very good reason for not releasing the whole of the Atlanta Report. We are not going to do it until we have to, and when there is an opportunity to reply to it, and that opportunity will not apparently be available until at least January.

So like you I regret that that has happened, but I don't know that there is anything more I can do than regret it. I don't want them to say any more. What they have said now --

MR. BROWN: Oh, I appreciate that and my remarks --

THE COMMISSIONER: -- has caused some trouble and --

MR. BROWN: My remarks of course were not directed to Commission counsel. I was simply voicing a concern over incorrect speculation, how that can occur, and I think perhaps a practical remedy is to avoid --

THE COMMISSIONER: Practical remedy is to prevent it from happening again.

We have now released not the Police report but we have released the minutes, have we not, in this matter?





C.2

1

2 MS. CRONK: Yes we have, sir.

3

4 THE COMMISSIONER: And blackened things  
5 out?

6

7 MS. CRONK: Well, actually in that  
8 case I think Mr. Lamek may have demonstrated another  
9 talent and taken scissors to them.

10

THE COMMISSIONER: Yes.

11

12 MS. CRONK: But I am not sure of that  
13 so I will check.

14

15 MR. YOUNG: Just to be clear, in the  
16 September 13th notes of the meeting involving the  
17 police --

18

THE COMMISSIONER: They were blacked out.

19

20 MR. YOUNG: I think they were blacked  
21 out in the latter case. Miss Cronk is absolutely  
22 correct.

23

24 Mr. Lamek's cut and paste, he did an  
25 excellent job.

17

18 THE COMMISSIONER: Well I guess we  
19 have learned something now and that is what we will do  
20 in future.

21

22 All right. Thank you. Miss Cronk?

23

24 MS. CRONK: Q. Dr. Kauffman, yesterday  
25 at the end of the day we were discussing the case of  
Kevin Pacsai and as you may recall you had outlined





C.3

1

2 for us first what your conclusion was in this case,  
3 and secondly the basis for it.

4 You will recall, Doctor, in this case  
5 as well that in addition to both the ante mortem and  
6 post mortem serum digoxin levels which were available  
7 and to which you referred there are available digoxin  
readings in fixed tissues.

8 In the report prepared by the Centre  
9 for Forensic Sciences dated January 11th, 1982, a  
10 concentration of digoxin in the amount of - ranging  
11 in the amounts of 102 to 105 nanograms per gram were  
12 recorded for the heart; that is fixed tissue, and as  
13 well a pure digoxin reading of 48 nanograms per gram  
14 was recorded in fixed lung tissue.

15 I take it, Doctor, obviously you had  
16 those concentrations and that data available to you  
17 at the time you were assessing the case?

18 A. Yes, I did.

19 Q. In addition, however, Dr.

20 Kauffman, in a report dated September 29, 1982 from  
21 the Centre for Forensic Science (that is Exhibit 95E,  
22 sir) Mr. Cimbura reported a digoxin concentration of  
23 122 nanograms per gram in frozen lung tissue.

24 As I heard your evidence yesterday you  
25 did not refer to that concentration or that specimen.





C.4

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Were you aware of that level at the time that you were assessing this case originally?

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A. No, I was not aware of that when I drafted the first report.

5

Q. Right. And, Doctor, were you subsequently informed with respect to that data?

6

A. Yes, I was subsequent to submitting a report.

7

8

Q. All right. And were the implications of that level then considered by you prior to the delivery of your second reporting letter to Mr. Wiley?

9

A. Yes, it was.

10

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Q. And once you learned of the reading and reassessed this case in light of that reason, Doctor, can you help us to what your conclusion then was?

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A. I don't think it changed my original conclusion substantively. It supported it and tended to increase the probability of my conclusion being correct, but I saw it as supporting data, hence supporting the initial impression I had gained from the other information.

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Q. And, Doctor, if we turn to page 3 of your second reporting letter to Mr. Wiley in the





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2 first full paragraph set out on that page dealing  
3 with Kevin Pacsai, you indicate with respect to the  
4 lung tissue concentration:

5 "Therefore, the concentration in the  
6 fresh autopsy lung is not definitive  
7 but supports the theory that this  
8 patient received a toxic dose of  
9 digoxin prior to death. The digoxin  
10 measurement in lungs does not change  
11 my original evaluation of the Pacsai  
12 case other than to strengthen it."

(2) Which of course is just what you suggested to us,  
12 Doctor.

13 The language of the second reporting  
14 letter, however, indicates that in the absence of  
15 knowledge of the fresh lung tissue specimen you had  
16 already concluded that it was probable that digoxin  
17 intoxication had contributed to this child's death.

18 Is that correct?

19 A. That is correct.

20 Q. May we turn then, Doctor, to the  
21 basis upon which you reached your initial conclusions.

22 You told us clearly that you were  
23 aware of the ante mortem blood sample with the level  
24 of greater than 10 nanograms. Is that correct?

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C.6

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Q. You told us as well that you were aware of the post mortem serum levels which ranged from 24 to 26 nanograms, the mid point being 25.5 nanograms as tested both at The Hospital for Sick Children and at the Centre For Forensic Sciences.

Were you also aware, Doctor, that the same post mortem specimen which resulted in a reading at The Hospital for Sick Children of 26 nanograms had been assayed for digoxin at Mount Sinai Hospital?

A. I was aware of that, yes.

Q. Were you then aware, Doctor, that a level of 112 nanograms was reported after several dilutions at Mount Sinai Hospital on that specimen?

A. Yes, I was aware of that.

Q. What significance, Doctor, if any, did you attach to the reading from Mount Sinai Hospital?

A. It was so out of line with the assays performed at The Hospital for Sick Children and the Centre for Forensic Studies that I viewed it as outlier, an error if you will, and discarded it essentially from my consideration in making my conclusions.

Q. It played then I take it no





C.7

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2 part in the formulation of your opinion?

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A. I think that is correct, yes.

4

5 Q. And, Doctor, what significance  
6 did you then attach to the ante mortem level of  
7 greater than 10 and the post mortem levels on serum  
8 that had been recorded at The Hospital for Sick  
9 Children and the Centre for Forensic Sciences?

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A. I think that is correct, yes.

Q. And, Doctor, what significance  
did you then attach to the ante mortem level of  
greater than 10 and the post mortem levels on serum  
that had been recorded at The Hospital for Sick  
Children and the Centre for Forensic Sciences?

A. The ante mortem level of 10 I  
had no way of knowing if that was 10 or something up  
to as much as 25 which reflected the post mortem  
concentration. So I had to assume that the real  
concentration ante mortem was somewhere in that range.

I could not really go further than  
that. When I estimated possible doses which could  
have accounted for this, I picked a middle concentration  
in the mid part of that range, but I had no way of  
knowing specifically where within that range the real  
number may have been.

Q. Well, we will come back to this,  
Doctor, but as I understand it when you came to  
actually to attempt the amount of dose that might  
have been given to the child you chose a mid point  
for the ante mortem serum concentration of 15 nanograms?

Do I have that correctly?

A. That is correct.





C.8

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Q. Doctor, in your view was the post mortem serum level of 26 nanograms consistent with the ante mortem serum level of greater than 10?

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A. Yes, I thought it was.

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Q. Doctor, we have heard as you know evidence from a number of biochemists from The Hospital for Sick Children. One of those, Dr. Ellis, has told us in evidence that at the time that the ante mortem specimen was being tested two dilutions were run and there was then from that point forward insufficient sample for further dilution.

He has said as well that there is a number recorded in the laboratory digoxin books beside the actual level. The number recorded is 10.6.

He has told us in evidence that that may be representative of the number extrapolated by the computer when the computer plotted out the graph although there was no further possibility of further dilution.

He has suggested therefore, in evidence, Dr. Kauffman, that the actual computer extrapolated number could have been first 5.3, which on a dilution of 2 would make the actual reading on the ante mortem sample of 10.6; or, alternatively, the actual computer extrapolated number could have been 10.6

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which on a dilution of 2 would make the actual ante

3 mortem reading approximately 21 to 22 nanograms.

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Do you understand the evidence so far  
as I put it to you?

6

A. I think so.

7

Q. All right.

8

Doctor, if in fact the ante mortem  
9 reading was 10.6 nanograms after all dilutions were  
10 complete, and the post mortem levels we know were  
11 between 24 and 26 nanograms, I take it we can agree  
12 that would reflect a multiplier effect or a post mortem  
elevation of something less than 3?

13

A. If I knew for certain that the  
ante mortem level was 10.6 and then was presented with  
post mortem concentrations in the serum of 25, I  
could very well accept that. I have no problem with  
that. That is well within the range of changes that  
are reported post mortem.

18

Q. And that I take it would be the  
case when we are considering the multiplier effect  
if the ante mortem level was in fact 21 or 22?

21

A. That is correct because as you  
know the multiplier and, the so-called multiplier - I  
don't like that term but I will use it - can be  
anywhere from no change to up to fourfold.

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2 Q. All right. Doctor, if the  
3 ante mortem reading was in fact 21 or 22 nanograms,  
4 apart from the multiplier effect, would that level in  
5 your view be consistent with the post mortem readings  
6 on serum that were actually achieved?

7 A. Yes. I have no problem with  
8 either of those numbers in terms of reconciling them  
9 with the post mortem concentrations.

10 Q. Doctor, may we turn then to the  
11 ante mortem potassium levels that were recorded for  
12 Kevin Pacsai. You alluded to those yesterday in  
13 explaining the basis for your assessment of this case  
14 and we know from the medical record of the child,  
15 Doctor, that on March 11th his serum potassium level  
16 was 3.9; on March 12th it was 9.0, but the evidence  
17 suggests that that was a hemolyzed sample; and on  
18 March 12th, later still in the day the level was 7.7.

19 If the potassium level of those  
20 numbers be accurate then, Doctor, it went from 3.9 to  
21 7.7 in something slightly over 113 hours. What  
22 significance if any, Doctor, did you attach to those  
23 levels when you were assessing this case?

24 A. At the time I was assessing the  
25 case, and I think I still agree with this with myself,  
I viewed that as being, the 7.7 as being a real change





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2 from the 3.9. It concerned me that it had changed  
3 for a 12 to a 13 hour period. I looked to see if there  
4 was any evidence that the child had decreased kidney  
5 function because that could have helped explain it.  
6 I couldn't explain it that way because his blood  
7 urea nitrogen is reported to be normal on two  
8 occasions, including the time of that high potassium  
9 level.

10 I looked to see if he had any degree  
11 of acidosis or hypoxia which could explain the high  
12 potassium level and, again, a blood sample obtained,  
13 it looks like approximately two hours prior to the  
14 second potassium sample. His blood gases were normal,  
15 his pH was 7.7, his oxygen was 161, which is quite  
16 high but I think he was getting some additional  
17 oxygen.

18 So, he had neither hypoxia nor  
19 acidosis documented around this time and I couldn't  
20 account for the high potassium based on those criteria.

21 So, putting it together with his  
22 clinical symptomatology, with the elevated digoxin  
23 concentration which was also drawn around the same  
24 time, I had to conclude that the most probable explanation  
25 was that the potassium elevation was a part of  
the digoxin intoxication.





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Q. Could renal failure, Doctor,

or a form of renal failure account for an elevated serum potassium level of the kind seen in this child?

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A. It can if it is severe enough

and for a prolonged period of time, yes.

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Q. And if the child were experiencing any degree of renal impairment or renal failure, would you expect to see changes in the blood gases of the child?

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A. Not necessarily the blood

gases; you might. Children with certain kinds of renal failure can have some degree of acidosis but not necessarily, depending on what kind of renal failure you are talking about. But I would have expected to see some degree of evidence of renal failure if it was responsible for the high potassium. I don't know if I have answered you or confused you.

Q. No, I think you have, Doctor.

I take it then that one possible explanation then for high serum potassium, apart from renal failure, is then acidosis or hypoxia?

A. Yes, high potassium can be a

result of severe acidosis. As I said yesterday, with acidosis there is an increased concentration of hydrogen ions, they tend to exchange in the cell and





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2 are exchanged for potassium which comes out of the  
3 cell and that makes the serum concentration of potas-  
4 sium go up.

5 Q. All right. And it was for that  
6 reason then that you addressed specifically the blood  
7 gas levels of this child over the two days of his  
hospitalization?

8 A. Yes, that is correct.

9 Q. All right. Doctor, what about  
10 the BUNs of this child, did you review those as well?

11 A. Yes, I did.

12 Q. All right. Could I ask you  
to turn to page 81 of the medical record first.

13 A. I don't have a copy of the  
14 medical record with me.

15 Q. All right.

16 I'm sorry, Mr. Registrar, that is  
17 Exhibit 106. Oh, it's here. K

18 A. Oh, it's here. Which page, 81?

19 Q. 81, Doctor. This child was  
20 admitted to The Hospital for Sick Children on March 11th,  
21 Doctor.

22 A. Yes, I see.

23 Q. All right. And on page 81 we  
see do we not one BUN reading for March 11th and one

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2 again for March 12th, both less than 5.

3 A. Yes, that's correct.

4 Q. What significance do these  
5 levels have for you, Doctor?

6 A. I think they are normal for an  
7 infant this age.

8 Q. Doctor, in assessing the  
9 blood gas history of the child, if you will, during  
10 life and as well the possibility of renal failure,  
11 did you take into account what the levels had been  
12 at McMaster Hospital prior to referral to The Hospital  
13 for Sick Children?

14 A. Yes, I had.

15 Q. And what was your view of the  
16 levels recorded at the referring hospital some days  
17 prior to admission to The Hospital for Sick Children?

18 A. Are you talking specifically  
19 about blood gases or BUN or....?

20 Q. Let's deal with blood gases  
21 first, Doctor.

22 A. All right. I was aware that  
23 upon his admission to McMaster he had been severely  
24 acidotic, as I recall a pH in the neighbourhood of  
25 6.9. As I recall from the summary of his course there  
and his medical record this degree of acidosis was





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2 slowly corrected over the next several hours and he  
3 was eventually returned to a normal pH before his  
4 transfer from McMaster. That was approximately three  
5 days prior to his admission to Sick Children's I  
6 believe, correct me if I'm wrong.

7

Q. That is my understanding,  
Doctor, that the levels were reported on March 8th.

8

A. Right. So, I took this into  
9 consideration but I thought that an acidosis, an acute  
10 acidosis which was corrected over several hours three  
11 days prior and the child had documented normal blood  
12 gases subsequent to that, at least when they were  
13 measured, that I couldn't account for any high  
14 potassium on the 12th March due to an acidosis four  
days earlier.

15

16

Q. And did you, Doctor, with  
respect to the --

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A. Pardon me, especially since he  
had had a normal potassium documented 12 hours prior  
to that high potassium.

19

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Q. On March 11th?

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A. Right.

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Q. Doctor, did you, in addressing  
the BUN levels taken at McMaster Hospital, have any  
concerns at that stage that he might have been





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2 evidencing some degree of renal failure?

3 A. Excuse me, I will have to refer  
4 to the BUN levels from McMaster, I don't recall those  
5 specifically. I should look at them before I answer  
6 you. Can you refer me to the page or information on  
7 the BUN?

8 Q. The blood gases, Doctor, are  
9 set out at page 38 of the record and at pages -- I am  
10 not sure if page 42 would help you, Doctor.

11 A. My copy of page 42 is illegible.

12 Q. I am showing you my copy of  
13 page 42, Doctor, and on the right-hand side of the  
14 page towards the bottom recorded I believe for March  
15 8th, 1981, are the BUN levels taken at McMaster  
16 Hospital.

17 A. Yes, that is correct. The  
18 BUN was recorded as 31 and the creatinine, which is  
19 another measurement of kidney function, was 1.3. The  
20 creatinine concentration is elevated for a baby this  
21 age, as is the BUN, which indicates that the child was  
22 experiencing, at least temporarily, some degree of  
23 decreased renal function at that point in time. This  
24 isn't surprising since his cardiac output was drama-  
25 tically reduced at that time due to his arrhythmia and  
it is consistent with the acidosis that was observed





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2 at the same time. Apparently his kidney function  
3 corrected then after his heart problem was corrected  
4 at the same time.

5 Q. And we see, Doctor, that in the  
6 period between -- and to help you, I stand to be  
7 corrected, but I don't think there are any other BUN  
8 levels recorded for March 9th and March 10th, but  
9 certainly on March 11th we have seen that the level  
was down to less than 5.

10 A. That is correct.

11 Q. All right. I'm sorry, that is  
12 the only level we have seen and it was repeated on  
13 March 12th and again it was less than 5.

14 A. Yes.

15 Q. All right. Doctor, as I under-  
16 stand it in this case you did as well attempt to  
17 estimate both the amount of a minimum dose of digoxin  
18 which could account for the serum and tissue levels  
19 in this child and as well to estimate the likely amount  
20 of administration of the digoxin. Do I have that  
21 correctly?

22 A. Yes, that is correct.

23 Q. May we deal first, Doctor,  
24 with your conclusions regarding the likely method of  
25 administration of the drug.





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A. I couldn't be certain on this child whether it might have been given by injection or orally. I think the possibility is equal either way. I felt from his course as described in the chart that it was unlikely that he received a large bolus close to the time of his death and that impression was affirmed by the fresh lung tissue specimen, which indicated to me that there had indeed been significant distribution to the tissues prior to his death.

So, I really couldn't make a distinction between whether or not he might have received a dose parenterally or orally.

Q. Are the digoxin concentrations found both in the fixed and frozen tissues of this child, Doctor, consistent in your view with a dose administered several hours prior to the onset of his critical symptoms?

A. I think it is consistent with several hours prior to or even a little bit longer.

Q. Well, you have told us, Doctor, that it was your opinion having regard to what you perceived to be the distribution of digoxin to tissues that a large bolus administered intravenously was unlikely. Were you able to put a time frame based on the information available to you on the most likely





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2 time of administration of the drug?

3 A. I really couldn't pin it down  
4 very well. When I looked at it, I had the impression  
5 from looking at the description of the events over  
6 approximately a 12-hour period prior to his arrest  
7 that there was something happening as early as 3:30, 3:45  
8 that morning when the nurse described him as being  
9 very different from what he had been before and being  
10 limp and so forth. It appeared to me that that could  
11 possibly be the beginning of intoxication symptoms  
12 which then progressed over the subsequent hours to  
13 varying degrees of dysrhythmia, ultimately culminat-  
14 ing in an arrest from which he could not be  
15 resuscitated.

16

17 If I accepted that relatively slow  
18 progression of events rather than the sudden  
19 catastrophic description which existed in some of the  
20 other cases, then it made most sense to me that he  
21 might have received a dose orally some six to twelve  
22 hours prior to the onset of this dramatic change in  
23 his condition. But I couldn't pin it down with any  
24 confidence more tightly than that.

25

Q. Doctor, what are you regarding  
as the onset of this change in his clinical condition  
that you have described?

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A. In that scenario I was regarding  
the change in his condition described at approximately  
3:45 to four o'clock the morning of the 12th of March.

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Q. Could I ask you, Doctor, to take  
a look at the progress notes of this child commencing  
at page 65. Do you have that, Doctor?

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A. Yes, I have page 65.

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Q. You will see there in the

middle of the page a nursing note for the period 3:45  
in the morning to six o'clock and as well back on  
page 63 a note by Dr. Costigan as to events at 5:30  
in the morning. Do either of those notes help you  
in terms of what you were regarding as the significant  
alteration in condition which you have described?





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A. I was referring specifically - well, I took all of this into consideration, but I was referring specifically to the note in the middle of the page on page 65:

"0345-0600 March 12/81".

Where a comment is made:

"...attempted to feed babe and his behaviour was entirely different from the other two times. He was lethargic and limp in my arms."

His apical rate - "...very irregular, monitor was showing bouts of tachycardia alternating with periods of bradycardia and rhythm strip showed occasional 2 to 1 block."

Then more descriptions subsequent to that. From the chart there seemed to be a distinct change from what had occurred from his condition earlier following his admission.

Q. I suppose the difficulty that we have, Doctor, is that the nursing note on that page covers a matter of several hours in describing those symptoms, and it is not I suggest clear from that note as to when those symptoms actually took place, when those manifestations actually took place?

A. That is correct.





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Q. But we know from page 63 do we not, that when Dr. Costigan made his note recorded to be at 5:30, that he was recording having seen the child because of anxiety and the bradycardia, and he then described the drop in blood pressure and the varying arrhythmias recorded on the rhythm strip?

3

A. Right.

4

Q. That is at 5:30 at night?

5

A. Right. So there is some

6

ambiguity as to the exact time that these symptoms evolve, and I suspect that they evolved over a period of time from the time they were first noticed until they are described, or have been described by several observers.

7

Q. Doctor, could I refer you please as well to page 8 of your first report to Mr. Wiley. In the portion of the report dealing with Kevin Pacsai, in the third full paragraph, the issues of the likely dose and the likely time of administration are addressed. You indicate midway through that paragraph that in your view:

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"...the development of hyperkalemia over a 12-hour period in the absence of severe renal failure suggests digoxin was given some hours before

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"the onset of critical symptoms".

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Do I correctly have it, Doctor, then, that quite apart from the concentration of digoxin found in the fresh lung tissues, that you thought that the development of the hyperkalemia as well suggested a more progressive development of digoxin toxicity?

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A. Yes, that is correct.

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Q. And, Doctor, you have suggested as I read it in the next sentence, that this child could have received an excessive dose of digoxin orally at the time that he received his last prescribed dose, that is 11 o'clock, 11:00 p.m. on the evening of March 11th, do I have that correctly?

A. Yes. It occurred to me that

in looking, trying to look at all the possibilities that one alternative was that he could have received an excessive dose at a usual dosing time rather than a non-scheduled dose being administered, since I felt that the highest probability was that he had received it some time, some hours prior to development of his symptoms.

Q. And you suggested as well,

Doctor, as I read your report, that he could have received an excessive dose at both prescribed dosing





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2 times on March the 11th, in this case that would make  
3 it at 9:00 a.m. and 11:00 p.m. when the doses appear  
4 to have been administered to the child, is that your  
view?

5

6 A. I thought that was another  
possibility, yes.

7

8 Q. The medication record for  
9 Kevin Pacsai, Doctor, indicates that on March 11th -  
10 perhaps I would ask you to turn to this, this is at  
page 80 of the medical record. Do you have that,  
11 Doctor, page 80?

12

A. Just a moment. Okay.

13

14 Q. The medication and treatment  
record indicates that at 11:00 p.m. on March 11th  
15 the child received .02, is that milligrams, Doctor,  
orally?

16

17 A. I assume that is milligrams,  
I see mgm, then po BID, so I assume that is milligrams.

18

19 Q. And appears as well to  
have received a like amount at 9:00 a.m. that morning?

20

A. That is correct.

21

22 Q. Doctor, dealing only for the  
moment with the dose at 11 o'clock on March the 11th,  
is that amount, the amount recorded ---

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THE COMMISSIONER: I am sorry, is

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5 2 this possible?

3 MS. CRONK: I am sorry, sir.

4 THE COMMISSIONER: I don't understand  
5 this. They are all dated the 11th of March but the  
6 9:00 a.m. one is that - I am sorry.

7 MS. CRONK: My understanding Mr.  
8 Commissioner, was that at 9:00 a.m. on March the  
9 11th the child received a maintenance dose in that  
10 recorded amount and then he received a second at  
11 that evening.

11 THE COMMISSIONER: Yes, that is all -  
12 yes, all right.

13 MS. CRONK: That pertains of course  
14 only to the digoxin. He received a number of other  
15 medications as noted.

16 THE COMMISSIONER: That was 11 that  
17 evening?

18 MS. CRONK: 2100 hours.

19 THE WITNESS: I am confused.

20 MS. CRONK: I am sorry, 9, I am saying  
21 11, it is 9. You are quite right, sir, the  
22 mathematical error, the timing error is mine.

23 THE WITNESS: I am confused, I am  
24 not sure what actually happened here. Because on  
25 medication sheets like this, when the order is written





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2 off, at least in our Hospital, the way the drug is  
3 to be given is written on the medication sheet just  
4 as it is here and the times that it is to be given  
5 in the future is written, and then it is initialled  
6 only at the times that it is actually given. It  
7 appears to me from this note that the first dose,  
8 the word "start" is there and the nurse's initials  
9 underneath it, the first dose was administered at  
10 2100 on the 11th.

11 Q. And that it is possible ---

12 A. No dose was given at 900 on the  
13 11th, that was simply the time from the order that  
14 it would be given subsequently.

15 Q. I see. Well, dealing then,  
16 Doctor, just with the dose which you feel most likely  
17 to have been given, at least as recorded, the one  
18 at 9:00 p.m. that evening; if the amount that is  
19 recorded in the medication treatment record was in  
20 fact the amount that was given, that is if .02  
21 milligrams was given to the child, could that  
22 account for the ensuing clinical course and serum  
23 digoxin levels found in this child?

24 A. No, I don't think so.

25 Q. Doctor, if at that time -

26 well leaving aside then for the moment the issue of

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2 an excessive dose; as I understand it you did attempt  
3 to calculate what in your view was the very minimum  
4 dose that the child could have received to achieve  
5 those levels?

6

7 MR. OLAH: Perhaps my friend  
8 before she proceeds, would like to put the  
9 time that the potassium sample was taken at 1745  
10 the evening before, that may assist the Doctor in  
11 terms of the time parameters that he places on the  
12 administration, the possible administration of  
13 digoxin.

14

15 THE COMMISSIONER: This is the level  
16 of, what page are we on now?

17

18 MR. OLAH: Page 81 Mr. Commissioner  
19 and you will see in the third column, the venous  
20 sample is taken at 1745 p.m. on March the 11th.

21

22 THE COMMISSIONER: 5:45 3.9 you  
23 mean?

24

25 MR. OLAH: It is the 3.9, and I  
am just wondering whether that would assist the  
Doctor in terms what outside parameter on when  
possibly digoxin was administered.

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27 MS. CRONK: Q. I am sorry, Doctor,  
28 I am not sure that I follow this.

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30 A. I am not sure that I do, either.

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THE COMMISSIONER: The point is that apparently if the potassium was 3.9 at 5:45 it is unlikely that the digoxin had been administered at that time.

MR. OLAH: Or prior thereto.

THE COMMISSIONER: Yes.

THE WITNESS: I would agree it is unlikely. I think we have to remember that hyperkalemia is not a consistent finding in digoxin intoxication, it may or may not occur. So I think the normal potassium, the potassium in the normal range and I am talking in generalities now, not this specific case necessarily, but in general, you can't assume because the potassium is normal that there was or was not digitoxin toxicity present, and I just wanted to qualify any conclusions that might be drawn by saying that.

THE COMMISSIONER: Possibly the fact that the potassium level did rise at the same time as the digoxin level might indicate perhaps in this particular instance there was a relationship.

THE WITNESS: Yes I think that is a likely possibility.

MS. CRONK: Q. And to follow my friend's thought further, Doctor, it is clear that





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2 by 6:30 the following morning, even though the  
3 sample taken at that time was slightly hemolyzed,  
4 we see a marked increase in what the serum potassium  
5 level was?

6 A. Yes. I think there is no  
7 doubt looking at the two levels at 6:30 and 7:20  
8 that the potassium was really elevated by 6:30 the  
9 following morning. That level was a little bit  
10 erroneously high because of the slight hemolysis,  
11 but I still think it reflected a true elevation of  
12 potassium. So I think what I was assuming when I  
13 evaluated this, at least looking at the potassium  
14 was that if a toxic dose of digoxin was administered  
15 it was some time during that 12 to 13 hour period;  
16 if that addresses your question.

17 Q. Thank you, Doctor. Doctor,  
18 I will return then in a moment to the suggestion that  
19 you have raised as to an excessive dose having been  
20 given to the child at 9:00 p.m. on the evening of  
21 March the 11th.

22 May we deal however for a moment with  
23 your own calculations as to what you feel to have  
24 been the minimum dose which could have been given to  
25 the child to produce the levels that we see in  
serum and the tissues. You have done as I understand





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2 it those calculations and have reported upon them to  
3 Mr. Wiley; do I have that correctly?

4 A. I believe so, yes.

5 Q. And I refer you, Doctor, to  
6 the last paragraph commencing at page 8 of your  
7 first report to Mr. Wiley. Could you help us first  
8 as to what the minimum dose was that you calculated  
9 in this case?

10 A. The minimum dose made from  
11 my assumptions was, and I was talking about an oral  
12 dose in this situation, .7 milligrams which would be  
13 contained in 14 millilitres of the paediatric oral  
14 elixir.

15 Q. For the benefit of those,  
16 Doctor, looking purely at your first report at the  
17 moment, as I understand it the actual numbers were  
18 changed in your second reporting letter to Mr. Wiley,  
19 once again because originally you had done your  
20 calculations based on American preparation as opposed  
21 to Canadian.

22 A. No, it was an error but it  
23 was a typographical error.

24 Q. I am sorry.

25 A. Not because of different  
26 products.





Kauffman, dr.ex.  
(Cronk)

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Q. Right. So in any event, Doctor, once the typographical error had been corrected you were talking about a minimum dose of .7 milligrams in a volume of 14 millilitres?

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A. That is correct.

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Q. And that, Doctor, was with respect to, as I read your report, a dose of the oral elixir?

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A. That is correct.

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Q. You have also indicated, Doctor and this is at page 9 of your report, that that dose and that volume of the paediatric elixir would "be quite possible". Can you help me, Doctor, as to what you meant with that statement?

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A. Okay. The description of

this infant prior to him being described as sick, some time the early morning of the 12th, was that he was taking feedings, was crying lustily and was sucking well. So it seemed to me that it would be quite in the realm of possibility for him to be given this type of volume orally and have him retain it, because his condition seemed to be, according to the description on the chart, of an infant who would be able to swallow it and retain this volume of fluid.

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Q. And Doctor, having regard to the amount that was actually prescribed to be given at 9:00 p.m. on March 11th, .02 milligrams, assuming that your minimum dose was the dose he received, that would be greatly in excess of the amount of prescribed dose, would it not?

A. That is correct. The concentration of digoxin in the paediatric elixir is .05 milligrams per millilitre and he was receiving .02, so that would be contained in a volume of .4 millilitres. So his prescribed maintenance dose would be contained in a volume of .4 millilitres.

Q. Whereas the dose that you are postulating as the minimum would be contained in a volume of 14 millilitres?

A. That is correct.

THE COMMISSIONER: I am a little lost, what is the correction that should be made and where should it be made in this?

THE WITNESS: Oh, in the first partial paragraph at the top of page 9.

THE COMMISSIONER: Yes.

THE WITNESS: The fourth line down.

THE COMMISSIONER: Yes.

THE WITNESS: Says, "With these













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13 2 assumptions a dose of approximately .133" and that  
3 should be "0.719".

4 MS. SYMES: Could you say that again  
5 please.

6 THE COMMISSIONER: 0.133 on the fourth  
7 line on the 9th page.

8 MS. SYMES: Could you give me the  
9 correct number please.

10 THE WITNESS: The correct number  
11 is 0.719.

12 MS. SYMES: Thank you.

13 THE WITNESS: And on the last line  
14 of that same paragraph the correct volume is 14  
15 millilitres rather than 2.5 to 3.

16 Q. And both of those corrections,  
17 Doctor, as I understand it were outlined by you in  
18 your second reporting letter to Mr. Wiley?

19 A. That is correct.

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Kauffman, dr.ex.  
(Cronk)

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Q. Doctor, may we then just go back for a moment to the calculations you just described for us, and let's look at the amount of the dose that was prescribed to be given at 9:00 p.m. on March 11th.

We know that is described in the medication treatment record as being .02 milligrams to be given orally.

A. That is correct.

Q. In what volume would that be contained in, Doctor, having regard to the forms of elixir that were available?

A. That dose would be contained in .4 millilitres.

Q. All right. And you had concluded, Doctor, that the minimum dose in your judgment that would be required to result in the levels found would be contained in 14 millilitres. Do I have that correctly?

A. That is an estimate given the assumptions I outlined.

Q. Right.

A. It could be a little less, it could be considerably more than that, depending on what assumptions you want to put into the formula.





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3 Q. I take it then, Doctor, if we  
4 postulate for the moment that an excessive dose was  
5 given accidentally in error to this child at 9:00 p.m.  
6 on March 11th, it would have to be a mistake involving  
7 a considerably larger volume of digoxin than had been  
prescribed?

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A. That is correct.

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THE COMMISSIONER: About 30 times.

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THE WITNESS: Yes, it is an

inconceivable error because the individual would have  
to use a different container to administer.

MS. CRONK: Q. Doctor, you referred  
a moment ago to the assumptions you made in calculating  
this dose and told us I think that if the assumptions  
were an error the dose might be a little bit more or  
a little bit less.

May we turn first to the assumptions  
which you did make and could you briefly outline those  
for us, please.

A. The assumptions included  
that the dose was given orally and since it was given  
orally 70% of the dose was absorbed.

I assume a serum half life of 30 hours  
again. I assume that distribution had essentially  
been completed so that the volume of distribution





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I used was 10 litres per kilogram, the same as I had used in other infants.

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I picked a mid-point for time within that 12 hour period, and a time that would allow complete distribution, and so I selected 6 hours to plug into the formula.

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I assumed because I didn't have any certainty what the real number was, that the concentration at the time of death was 15. I think based on what you told me you could legitimately assume 10.6 or 22, and your numbers will come out a little differently, but I don't think that the basic judgment is any different. And I assumed an elimination rate constant the same as I assumed in the past of 0.231.

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Q. Doctor, would we correctly infer from the assumption you made that the dose was given orally, that that was in your view the most likely method of administration?

18

A. That was my feeling, yes.

19

Q. You have told us, Doctor --

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A. But I think there is virtually an equal probability that it could have been given intravenously some time prior to...

21

Q. I understand, Doctor, excepting always the possibility of an intravenous large bolus

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dose shortly prior to the onset --

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A. I couldn't reconcile that with  
the picture I saw, no.

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Q. Doctor, as you know,

Dr. Spielberg has testified with respect to a number  
of these children including Kevin Pacsai.

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He has suggested in his evidence that  
one possible explanation for Kevin Pacsai's levels  
both in serum and in tissue and of the fact that he  
re-established sinus rhythm following his transfer to  
the Intensive Care Unit is that he may have received  
an excessive dose of digoxin. This is found,

Mr. Commissioner, Volume 55, page 2314.

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THE COMMISSIONER: Yes, but that is  
not quite what he said. You haven't finished what  
he said?

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MS. CRONK: No, I haven't finished.

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Q. That is possibility number one.

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He has suggested as well, Doctor, that another  
explanation might be that increases in the serum  
digoxin levels of the child might have occurred as  
a result of loss of digoxin during life from tissues.

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I would like to read a portion of his  
evidence to you in that regard. It is found at  
Volume 55, page 2315, sir.





Kauffman, dr.ex.  
(Cronk)

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Commencing on the fourth line, this  
was Dr. Spielberg's evidence, Dr. Kauffman, on this  
possible explanation:

5 "I think the other possibility has to  
6 be considered, that in light of other  
7 babies that we have now seen, as well  
8 as the published literature that  
9 increases in serum digoxin level from  
10 tissue loss may have occurred in this  
11 baby, thus the baby's serum concentra-  
12 tion would have been increased, but  
13 the concentration at his myocardium  
14 might not have been increased, and in  
15 fact might have been slightly decreased.  
16 Because again to go to a level of 10  
17 or 20 from a level of 1.8 is a very  
18 tiny fraction of loss of digoxin as  
19 we discussed yesterday. We are not  
20 talking about massive digoxin release,  
21 we are talking about probably two per  
22 cent, maybe three per cent, very, very  
23 small amount of release, from mechanisms  
24 that again in honesty we don't under-  
25 stand except that we have seen it in  
other patients.





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"Thus we have a situation where the baby's total body digoxin was the same, but where his serum level in fact was higher. Under those circumstances I find it easier to imagine the child going back into sinus rhythm. The fact that he then reverted to an abnormal rhythm is basically what had been happening to the child all along. In fact the child had tremendous rhythm disturbance and was going up and down, and up and down, and that he finally died from a rhythm disturbance is not surprising.

Thus I think the three possibilities that exists in the infant, that I have to at least consider pharmacologically (are) one, accidental or incidental administration of digoxin; and two, abnormal pathophysiology with a rising serum digoxin level as a result of phenomena that again we do not understand, but that in fact we see."

I would like to deal obviously,

Doctor, with the second possibility that Dr. Spielberg





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has advanced, and that is what he described as the  
abnormal pathophysiology of this child could have  
accounted for a redistribution or loss of digoxin,  
if you will, from tissues of the child, during life  
to serum accounting for elevated serum levels.

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I would like to refer you as well,  
Doctor, to page 9 of your own reporting letter to  
Mr. Wiley, the second paragraph dealing with Kevin  
Pacsai in which you had said:

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"The inherent dysrhythmia of this  
infant - "

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A. I'm sorry, where are you?

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Q. Page 9 of your first reporting  
letter to Mr. Wiley, and this is the --

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A. That doesn't --

Q. The second paragraph.

17

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A. Oh, the top of the page, okay.

THE COMMISSIONER: The first full  
paragraph.

19

THE WITNESS: Yes.

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MS. CRONK: Q. "The inherent

dysrhythmia of this infant probably

made him exquisitely susceptible to

digoxin-induced fatal arrhythmias. I

am aware of no evidence that no other





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"medication or other agent was administered which may have contributed to this child's death."

5

That was your opinion at the time I take it?

6

A. That is right.

7

Q. Doctor, in these circumstances and having regard to the opinion expressed by Dr. Spielberg and your own knowledge of this child's condition and disease state, could in your judgment his particular pathophysiology account for both the circumstances of his death and the digoxin levels found in tissues and in serum?

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A. I don't think so. At the time I wrote this report I was not considering the second hypothesis that Dr. Spielberg advanced. I subsequently have, of course, considered that and thought about it.

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What I meant in the first sentence of the paragraph you just read really had no meaning in relation to Dr. Spielberg's comments, and maybe I should address what I meant in that sentence.

This baby clearly had an underlying dysrhythmia problem. That was documented on admission to the other hospital, so with or without the digoxin he had a basic underlying problem.





Kauffman, dr.ex.  
(Cronk)

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Babies with various kinds of dysrhythmias, including the one this infant apparently had, are much more susceptible to drug induced arrhythmias which can be life threatening, and digoxin of course can do that.

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So what I was saying here is that this in fact could have had a life threatening arrhythmia induced by digoxin at lower concentrations than you might - than would produce a fatal arrhythmia in a child who had a normal heart. That was all I was saying.

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Q. I see.

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A. Now in response to the

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comments from Dr. Spielberg's testimony which you just read, I said I wasn't considering that hypothesis at the time I dictated this report. It was something that I had never thought about.

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Subsequently I have gone back over this case with that in mind and attempted to see whether I not could fit that concept into this particular case. There are several factors that make it difficult for me to agree with Dr. Spielberg's hypothesis in this specific case. One is that although this child had a life threatening arrhythmia at McMaster Hospital and was in severe acidosis, he recovered





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rather rapidly and was apparently physiologically  
normal at certain times subsequent to that event.

4

He had an anatomically normal heart  
at autopsy. He had normal blood gases when they were  
measured following that initial event when he  
almost died.

7

He had normal potassium level when  
it was measured on his admission here and then it  
subsequently went up over the next 13 hours.

10

At autopsy there was no description  
if I remember correctly of any significant myocardial  
damage so it is difficult for me in the absence of  
an anatomically abnormal heart, and the absence of  
acidosis and hypoxia, in the absence of evidence of  
myocardial damage at autopsy, to accept a hypothesis  
with any degree of probability that explains tissue  
redistribution out of the myocardium to explain an  
elevation in the serum.

18

I think one has to consider it and  
consider it seriously, but I just can't reconcile it  
with the facts as I see them. C-1

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Q. Doctor, I take it that you  
would agree that there can be cases where the particu-  
lar disease state of the child or his or her patho-  
physiology, to use Dr. Spielberg's language, could

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well account for an elevation in serum digoxin levels  
during life. Would you agree with that?

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A. A general answer to your  
question, I think that is possible, yes.

6

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Q. And, Doctor, having regard  
to the particular dysrhythmia from which this child  
was suffering that you yourself described as being  
(a) both inherent and (b) rendering him in your  
language exquisitely susceptible to digoxin toxicity,  
is not possible, Dr. Kauffman, that the underlying  
cardiac condition of this child was sufficient to  
cause tissue damage during life so as to cause that  
kind of release of digoxin?

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A. I suppose it is possible,  
but there is no evidence of it from the autopsy  
report that I am aware of, and I would expect to  
see some evidence at least microscopic that that  
had occurred.

18

Q. Yes.

19

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A. Maybe we can look at the  
autopsy report.

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Q. I would ask you, Doctor, if  
you would, to turn to page 94 of Pacsai's medical  
record. That is his preliminary autopsy report. The  
final autopsy report, Mr. Commissioner, is Exhibit 106A.





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I don't know whether --

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THE COMMISSIONER: I think it is  
right with it.

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MS. CRONK: Q. Doctor, we see  
firstly confirmation that at autopsy --

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A. I'm sorry, where are you?

8

Q. Page 94.

9

A. You are not on the exhibit?

10

Q. No, on page 94, the second  
paragraph under the short history.

11

A. Okay.

12

13

Q. We see confirmation that at  
autopsy the child's heart was anatomically normal.

14

Do you see that?

15

A. Yes.

16

Q. And then continuing with the  
description of what was seen at gross autopsy,  
there was presence of congestion in several organs,  
there were petechial hemorrhages of the thymus and  
recent hemorrhage of falx cerebri are most likely  
related to hypoxia.

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A. Right.

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Q. And then the discussion is  
about cultures.

23

A. Right.

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Q. And the absence of any evidence  
of infection.

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Could not the hemorrhages reflected  
in the gross autopsy and indeed in the final autopsy  
report constitute evidence of damage to the muscle  
or tissue of this child potentially sufficient to  
cause dislodging of digoxin from tissue?

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BmB.jc  
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A. I don't think ante mortem. I

think those are terminal agonal changes that are commonly seen in autopsy related to the hypoxia and acidosis that supervenes during the resuscitation and the death of the individual.

Q. Well, Doctor, I grant you that this ---

A. I don't think that we know that these were ante mortem changes.

Q. Doctor, I grant you that the pathology findings reported in this case on this aspect of it are quite different than for example we have seen in the case of Allana Miller where specific mention was made of extensive resuscitation trauma. However, I draw your attention to the findings under Anatomical Diagnoses and, in addition to the hemorrhages to which I have drawn your attention, mention is made of an infarction, described as an old one, to the left kidney cortex.

A. This is still on page 94?

Q. Yes, still on page 94, Item No. 6, Doctor, under Anatomical Diagnoses.

A. Yes.

Q. There is evidence of an old infarction to the left kidney and as well of stress on





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the thymus and presumably effect on the organ itself from that stress. Could either of those pathological findings in your view account for dislodging of digoxin from the tissues of the child?

A. I suppose it is possible. I think it is somewhat unlikely. During that three-day period the infarction is described as old. I don't know what is meant by that, whether it is days or weeks. This type of thing happens in kidneys sometimes due to reduced flow through the vessels to the kidney and may have indeed happened the four or five days previously when he was in shock at McMaster. The thymus in babies who are stressed commonly decreases in size over a period of time and I have no idea what the digoxin content is in thymus, I have never seen any data in which that was measured. But I suspect that the thymic change was a change that took place over a period of weeks, days to weeks prior to his, even maybe prior to his admission to McMaster because he was sick for several days even before he went in there and is a response to the illness and the stress that he sustained during that five, six day period.

Q. Doctor, you are familiar as I understand it with the case of Gary Murphy, a child who died at The Hospital for Sick Children in April of this year?

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G.3

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A. Yes, I am.

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Q. Indeed, as I understand it you  
3 testified at the inquest of that child?

4

A. Yes, that is correct.

5

Q. Is that correct, Doctor?

6

A. That is correct.

7

Q. Doctor, I would like to draw  
8 your attention to certain portions of your evidence  
9 from the inquest of Gary Murphy. Do you have a  
10 transcript of your evidence, Doctor?

11

A. I have a copy, I think it is  
12 the same.

13

Q. I would ask you if you would,  
14 Doctor, to turn to page 39. Do you have that, Doctor?

15

A. Yes.

16

Q. Doctor, as I understand it, you  
17 were asked at the inquest to outline what you felt  
18 might be possible explanations for the post mortem  
19 serum digoxin levels found in Gary Murphy and that  
20 you in fact did outline a number of possible  
21 explanations but that you preferred one and expressed  
22 a preference in terms of likelihood for one as opposed  
23 to the others. Do I have that correctly?

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A. That is correct.

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Q. And am I correct as well, Doctor,





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that the post mortem serum levels on this child were considerably elevated; indeed, at the Centre of Forensic Sciences they were as high as 32 nanograms per gram, although, the readings at The Hospital for Sick Children were 18.7, is that correct?

A. That is correct.

Q. All right. Doctor, your fifth and preferred hypothesis in this case, as I understand it, is recorded in outline at the top of page 39 of the transcript of your evidence. It reads:

"The fifth hypothesis or theory is that the gradual worsening of his cardiac condition, the continuing and progressive damage to his heart muscle, his increased lack of oxygen, which is called cyanosis, his reduced output of his heart, cardiac output, the profusion of his tissues resulted in damage to these tissues either functionally or in some cases by the autopsy actual cell death of some tissues, thereby releasing bound digoxin into the serum compartment or into the extra saline fluid which would then diffuse back into the serum."





G.5

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2 A. Saline is a typographical error,  
3 it was extracellular.

4

Q. And you continue:

5 "There is very little known, if any-  
6 thing, in the literature about the  
7 effects of these kinds of severe  
8 physiological derangements of the  
9 binding of digoxin and, so, it is  
10 difficult to present objective or  
11 conclusive evidence to support this  
12 hypothesis but from what is known  
13 about the characteristics of the  
14 binding sites I discussed this morning  
15 and the nature of the binding of  
16 digoxin to this material, this is  
17 certainly pharmacologically reasonable  
18 and rational."

17

18 Doctor, that was your preferred  
19 hypothesis or explanation for the elevated levels  
20 found in Gary Murphy, was it not?

21

A. That is correct. I think that  
22 to place that in context it is important to note the  
23 qualifications I put on that before I offered it.  
24 Gary Murphy was a very puzzling case to me and I wasn't  
25 alone in that. In looking at Gary Murphy he was, as





G. 6

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2 you know, I think six or seven months old at the time  
3 he died; he may have been a little older than that,  
4 I don't recall specifically. He had had severe  
5 cyanotic heart disease from the time of birth. He had  
6 an extremely unusually complex type of congenital  
7 heart disease or complex of congenital anomalies which  
8 caused him to be severely cyanotic from birth.

9 He progressively deteriorated during  
10 the several weeks prior to his death to the point  
11 where the surgeons and the cardiologists had apparently  
12 told the parents that there really wasn't anything  
13 curative that they could offer him and apparently  
14 from the chart the decision had been made to not be  
15 heroic with him since he could not be cured, keep him  
16 comfortable and not take the usual heroic measures  
17 to preserve his life. Because of that there is very,  
18 very minimal documentation on his chart regarding  
19 laboratory studies, including blood gases, electrolytes,  
20 blood urea nitrogen and digoxin levels because I  
21 suspect a minimal amount of manipulation was being  
22 carried out with this child simply to reduce his  
23 suffering.

24 So, we were handicapped in trying to  
25 assess his case because of a posity of objective data.  
In looking at the entire picture it was difficult then





G.7

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2 to come up with any clear explanation for the post  
3 mortem digoxin concentrations that were observed in  
4 this child.

5 So, looking at all the possibilities  
6 I couldn't explain it by renal failure, I had no data  
7 upon which to explain it by acidosis alone, although,  
8 I thought that he was probably acidotic in the hours  
9 prior to his death because of his severe and  
10 increasing hypoxia. So, I had to consider all the  
11 possibilities and the other four possibilities that  
12 I could think of, I couldn't reconcile with what  
13 information I did have and this was the only  
14 explanation that I could think of that I thought could  
15 fit the picture but I was never totally comfortable  
16 with it and I think I made that clear in my testimony  
17 at that time.

18

Q. I'm sorry, Doctor, I didn't

19

mean to imply that you were saying with certainty or  
20 certitude that that was the explanation for that  
21 child's levels.

22

A. I understand that, but I didn't  
want to let that misconception exist either. I think  
22 what I said in that testimony specifically about that  
concept has to be interpreted in the context of all  
23 the caveats I placed on it.

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Q. Well, Doctor, my point to you is simply this. Isn't the hypothesis which you preferred in the case of Gary Murphy in fact very similar to, if not identical, to the hypothesis, if you will, proposed by Dr. Spielberg as a possible explanation for Kevin Pacsai's levels? Aren't we talking about the very same thing?

A. As I understand his testimony, I think it is essentially the same, yes.

Q. All right. And aren't there as well, Doctor, a number of similarities between the case of Gary Murphy and Kevin Pacsai; first, both had elevated post mortem digoxin levels on blood specimens?

A. Yes. In reviewing the charts that's about the only similarity that I can see.

Q. Well, Doctor, let me perhaps suggest some others to you.

A. Okay.

Q. All right. Both had, as you have told me, an elevated post mortem serum level, and I suggest to you that the actual concentrations measured 26 nanograms post mortem as compared to 32 nanograms in Gary Murphy's case or 18 if you take The Hospital for Sick Children level, are, in a quantitative sense, relatively similar?





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2 A. I don't think we can differentiate  
3 between them really.

4 Q. And as well, Doctor, in neither  
5 case, as I have understood your comments just now  
6 about Gary Murphy, were you able to see any evidence  
7 of renal failure? That was not an explanation in  
8 Gary Murphy's case?

9 A. That is correct.

10 Q. And that is not in your judgment  
11 an explanation for Kevin Pacsai?

12 A. It is not an explanation. They  
13 both appeared to have normal renal function except we  
14 didn't have the data in Gary Murphy close to the time  
15 of his death like we do in Kevin Pacsai.

16 (2) Q. And you are referring to now ---  
17 A. We just didn't have the infor-  
18 mation.

19 Q. You are referring now to the  
20 blood gases or the BUN?

21 A. Blood urea nitrogen or the  
22 creatinine.

23 Q. All right. Doctor, as well, both  
24 of those children had underlying cardiac diseases of  
25 some severity?

A. That is correct, but the heart





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2 disease was extremely different, totally different.

3 You can't lump all heart disease in one category.

4

Q. All right. Well, Doctor, what  
5 I'm suggesting to you is, and I would like your  
6 opinion on this matter, having regard to the situation  
7 that you were most familiar with, equally familiar  
8 with, that is, Gary Murphy and your knowledge of  
9 Kevin Pacsai's clinical condition and the nature of  
10 his disease state, is it not possible in your view  
11 that Kevin Pacsai's pathophysiological condition  
12 could account for the elevated levels of digoxin that  
13 we see in that child?

14

A. I don't think so. Their patho-  
13 physiological conditions were very, very different.  
14 For example, Kevin Pacsai was much younger, Gary Murphy  
15 was six or seven months of age, and I can't remember  
16 specifically, but the major difference was that  
17 Gary Murphy's problem was a very complex anatomical  
18 lesion which caused him to be severely cyanotic all  
19 his life. He never had enough oxygen going to his  
20 heart.

21

In contrast, Kevin Pacsai had no  
21 anatomical abnormalities in his heart. He did not  
22 have hypoxia except the times when his cardiac output  
23 severely fell when he was so sick at McMaster. He

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2 has no other times when he has documented cyanosis.  
3 In fact, Kevin Pacsai had normal heart output when his  
4 heart was beating normally.

5 So that the two types of heart disease  
6 are so dissimilar. In my mind at least they really  
7 can't be compared at all, it is like comparing apples  
8 and oranges, or maybe no more different than that.

9 Q. All right, I see, Doctor, thank  
you, that's helpful.

10 Doctor, I am obliged to ask you if  
11 Gary Murphy had died in March of 1981 would his death  
12 have been one that you would have assessed as possibly  
13 involving digoxin intoxication?

14 A. I think he would have been  
15 assessed during that period of time because, as I  
16 understand it, every baby who died during that period  
17 of time was being very carefully looked at and  
evaluated.

18 Q. Doctor, in the course of the  
19 assessment, had you been reviewing Gary Murphy's case  
20 at that time for that purpose, would you, as best you  
21 can tell today, have then felt that digoxin intox-  
22 ication was the preferred explanation for his post  
mortem serum levels?

23 MR. HUNT: I wonder, Mr. Commissioner,

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if that kind of a question is really helpful at all to this Inquiry. First of all, to ask this witness to try to put something that was in a totally different context ---

THE COMMISSIONER: Well, he may not be able to, and I don't know how much help it is but I don't see anything wrong with the question, that is, if you can answer it, Doctor, in the state of your knowledge at that time as opposed to your knowledge now and if you can, say, would you be likely if you had been on the scene - is it on the scene? He wasn't on the scene of course until 1982 anyway.

THE WITNESS: No, I came in late in the course of the events.

MS. CRONK: I suppose properly speaking, the question I was struggling to put, Mr. Commissioner, and badly, is that if this had been one of the children amongst the 36 that you reviewed when you reviewed the others for Mr. Wiley, are you in a position to tell us whether you would have felt that digoxin intoxication likely contributed to his death?

THE WITNESS: Before I answer that I'm going to refresh my memory as to the criteria I was using for making those classifications, if I may.

MS. CRONK: Q. All right.





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A. Because I'm not sure what I

would have done then at that time with what I was  
aware of at that point in time. The best guess I can  
make is that I probably would have rated him - are you  
asking in terms of - I had better make sure I under-  
stand your question. Are you asking me in terms of  
evaluating him as I have the others in the Police  
report?

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Q. Yes I am, Doctor.

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A. Okay.

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2 Q. If he had been one of this  
3 group that you looked at all 36 --

4 THE COMMISSIONER: We are really  
5 looking at whatever date this is in 1982 I think you  
6 said.

7 MS. CRONK: January of this year, sir.

8 THE COMMISSIONER: January of 1983.

9 MS. CRONK: Was the second reporting  
letter.

10 THE WITNESS: December and January.

11 THE COMMISSIONER: Yes. All right.

12 THE WITNESS: I think I would have --

13 THE COMMISSIONER: Before you go  
any further --

14 THE WITNESS: Yes.

15 THE COMMISSIONER: -- it is legitimate  
16 for you to say you don't want to answer that question,  
17 but if you want to answer it I certainly want to have  
18 you answer it.

19 THE WITNESS: I don't mind answering  
20 it but I really don't know what I would have done at  
21 the time.

22 MS. CRONK: Q. I think that is the  
answer.

23 A. If I was forced to say you  
24 have got to tell me something, I could give you an

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1  
H2 2 answer.

3 THE COMMISSIONER: You are not  
4 forced, but if you want to give us an answer.

5 THE WITNESS: I think it is very  
6 speculative because I really don't know how I might  
7 have evaluated it at that point in time. It is hard  
8 to put yourself back in that frame of mind a year  
9 later.

10 MS. CRONK: Q. I think the matter  
11 is best left there, sir.

12 11 May we take our break?

13 12 THE COMMISSIONER: Yes. We will  
14 take 20 minutes.

15 13 MS. CRONK: Thank you.

16 14 THE COMMISSIONER: Oh, Miss Cronk,  
17 we have to make this an exhibit. The abstract from  
18 the proceedings, Exhibit 271.

19 17 --- EXHIBIT NO. 271: Abstract from proceedings  
20 of International Society for  
21 Clinical Pharmacology, July  
22 1983.

23 19 --- short recess.

24 20 --- Upon resuming.

25 21 THE COMMISSIONER: Yes, Miss Cronk.

22 22 MS. CRONK: Thank you, sir.

23 23 Q. Doctor, may we turn now please  
24 to the case of Kristin Inwood. In our discussion with





1  
2 respect to this child commences at page 11 of your  
3 reporting letter, your first reporting letter to Mr.  
4 Wiley.

5 As I understand it, doctor, when you  
6 delivered your first reporting letter you were of the  
7 view that the available digoxin levels of and in  
8 themselves were inconclusive regarding digoxin toxicity  
9 in this child; do I have that correctly?

10 A. That is correct.

11 Q. And you had available, so that  
12 we are clear, at that time the digoxin concentrations  
13 which had been measured in fixed heart tissues in  
14 Kristin Inwood?

15 A. That is right.

16 Q. And those levels, doctor, as you  
17 may recall I suggest were 230 nanograms per gram in  
18 the left ventricle; and 300 nanograms per gram in the  
19 septum dealing simply with the heart tissues. Does  
20 that accord with your recollection?

21 A. In the fixed tissues, right.

22 Q. And those levels I suggest  
23 further, doctor, are both within the range of levels  
24 reported by Mr. Cimbura in cases of fatal poisoning  
25 but as well are within the range reported by him for  
persons on digoxin therapy?





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2 A. That was his report, yes.

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Q. Is that correct, doctor?

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A. That is correct.

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Q. If we look at the actual levels,  
doctor, that is the 230 nanograms in the left ventricle  
and the 300 in the septum, I suggest that the con-  
centrations are in fact high.

6

A. They are higher than most of  
the fixed tissue specimens were, yes. That would lead  
you to believe --from talking to Mr. Cimbura I assumed  
that his true digoxin levels in fixed tissues represent-  
ed the least it might have been with no way of knowing  
how much more than that it might have been at death.

7

Q. You are suggesting these in fact  
might have been higher at death?

8

A. I would expect, yes, they were,  
the fixed tissues tend to leach out into the fixative  
and so that concentration in the tissue decreases  
with time as it sits in the fixative. So these  
concentrations would have represented the least it  
could have been at death, and very likely they were  
actually higher than that at death, but how much higher  
I have no way of knowing.

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Q. Am I correct, doctor, that when  
we compare the concentrations reported on Kristin

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H5 2 Inwood's fixed heart tissues quantitatively the numbers  
3 are higher than they are in the fixed tissue concentra-  
4 tions on any of the other children that we have looked  
5 at?

6 A. That is correct.

7 Q. And, doctor, does that neces-  
8 sarily imply with respect to this child that there was  
9 some time available prior to death for distribution of  
10 digoxin if it was administered to the child from the  
serum to the tissues?

11 A. Yes, I think that is the case,  
12 yes.

13 Q. Doctor, were you also aware at  
14 the time of doing your first reporting letter to Mr.  
15 Wiley of the ante mortem digoxin level which had been  
16 measured on this child the day prior to her death,  
and that level was 2.6 nanograms?

17 A. Yes, I was aware of that.

18 Q. Doctor, on the basis of what  
19 was known to you at the time that you delivered your  
20 first reporting letter to Mr. Wiley what was your  
21 overall conclusion regarding the involvement of digoxin  
in the death of this child?

22 A. I felt that, as you said, the  
23 fixed concentrations, although they were higher than  
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2 the other fixed tissue concentrations in other patients,  
3 were still inconclusive in terms of whether or not  
4 digitalis toxicity had been related to the death.

5 I also was aware that the type of  
6 heart disease this child had is not uncommonly  
7 associated with sudden death. So at that time I felt  
8 that in the face of the normal digoxin concentration  
9 the day before, and the fact that digoxin had  
10 ostensibly not been ordered for the child following  
11 that, that the probability of digoxin being responsible  
12 for this infant's death was low.

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Q. I take it it was still a  
possibility at that time that you were not prepared  
to discount entirely?

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A. I was not prepared to totally  
discount it but I thought the possibility was low.

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Q. And, doctor, as I understand  
it, subsequent to the delivery of your first reporting  
letter you became aware of a post mortem serum  
sample that had been tested by Mr. Cimbura, and it is  
recorded to have a digoxin concentration of 491 nano-  
grams per millilitre; is that correct?

A. Yes, I was subsequently made  
aware of that.

Q. And did that new information,





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H7 2 doctor, between the time of delivery of your first  
3 report and your second cause you to alter your  
4 opinion in this case?

5 A. Yes, it did.

6 Q. In what respect?

7 A. I thought it significantly  
8 increased the probability that this child had indeed,  
9 that her death was indeed related to digoxin intoxica-  
tion.

10 Q. Doctor, I ask you if you would,  
11 please, turn to page 3 of your second reporting letter  
12 to Mr. Wiley.

13 A. I have it.

14 Q. Do you have that, doctor?

15 A. Yes.

16 Q. And I draw your attention to  
17 the last sentence of the first main paragraph in which  
you say:

18 "The high serum digoxin concentration  
19 in the frozen post mortem venous  
20 specimen..."

21 A. I'm sorry, I am not with you.

22 Q. I am sorry. Actually it is all  
23 one paragraph and I apologize, doctor, about two-  
thirds of the way down the paragraph.

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Kauffman  
dr.ex. (Cronk)

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A. Yes.

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Q. You see where it says, "However,  
even if one assumes..."

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A. Yes.

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Q. Would you go please to the  
next sentence.

7

A. Okay.

8

Q. "The high serum digoxin concentration in the frozen post mortem venous specimen is a very important piece of data and strongly supports the theory of death due to digoxin intoxication which was originally based on the high fixed tissue concentrations and the hyperkalemia found the morning of death."

16

I suggest to you, doctor, that the language of that section of your report would seem to indicate that you had in the absence of the knowledge of the blood sample concluded that digoxin was likely involved in the death of this child; is that correct?

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A. I considered it as a possibility. Hyperkalemia was a factor, but the problem with the hyperkalemia was as I recall her pH was low, it was 7.14 or something like that close to the time that

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2 potassium was drawn. So I couldn't be certain if the  
3 hyperkalemia was -- might have been related to digoxin  
4 intoxication or to her acidosis. Although I had to  
5 take it in, I couldn't ignore it, I had to take it  
6 into account. I had to take into account her  
7 clinical course, but I did not have strong, at that  
8 time, in the first report, I didn't have strong  
9 digoxin data to support that theory so I had much  
10 less confidence in that theory than I did after I was  
11 made aware of the serum concentration of 491.

12 Q. Doctor, when you refer to the  
13 hyperkalemia in this child, are you referring to the  
14 serum potassium level which I recall was 7.3 on the  
15 morning of her death?

16

A. That is correct.

17

Q. Doctor, with respect to this  
18 post mortem blood specimen, you indicate in the first  
19 sentence of your report to Mr. Wiley that you had  
20 become aware of it and that it was a sample from the  
21 sagittal sinus which was apparently obtained from the  
22 infant at the time of autopsy and remained frozen for  
23 some months prior to performing a digoxin assay on the  
24 sample.

25

Can you tell me first, doctor, what  
the source of your information was that the sample





Kauffman  
dr.ex. (Cronk)

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H10 2 was from the sagittal sinus of the child?

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A. This was information provided to me by either Mr. Cimbura and/or the Crown Attorney staff, I don't remember exactly who the individual was. This was during a meeting that I had when I was discussing my original report to them.

Q. Doctor, I tell you that there is some doubt on the evidence adduced in these proceedings to date as to the source of that sample. One suggestion that has been raised is that it may have been taken by Dr. Glen Taylor at autopsy from the inferior vena cava of this child. Were that the case, and were it not to have been taken from the sagittal sinus, would that affect your conclusions or alter your thinking in any way with respect to the importance of the sample result?

A. I really don't think that would have any influence on my views of that sample.

Q. Doctor, you have said as well that the sample according to your information had remained frozen for some months prior to performing the assay. Once again, what is the source of your information in that regard?

A. As I recall it was the same source but I don't remember the individual, this was





Kauffman  
dr.ex. (Cronk)

Hill 1 information that was obtained during a group meeting.  
2 At that time I was getting all my forensic information  
3 of course through Mr. Cimbura or somebody on his  
4 staff, so I don't remember exactly who gave me that  
5 specific information.  
6

Q. Doctor, what significance, if  
7 any, do you attach to the fact that the sample may  
8 have been frozen for a period of several months?

A. Well, in view of the extremely  
10 high concentration that was measured, and in view of  
11 questions about how it had been stored, I had to think  
12 of possibilities in terms of how the sample was  
13 handled that might have accounted for, at least in  
14 part for the high concentrations. Actually I didn't  
15 mention this specifically in this paragraph, but as  
16 I recall, and this is only my recollection a year  
17 later, but as I recall that discussion included the  
18 possibility that the sample might have been frozen,  
19 or it might have been refrigerated. As I recall the  
20 possibility was raised that maybe the container of  
21 that sample had not been capped so that it was open  
22 during the storage time. There were a lot of un-  
23 certainties about exactly how the sample had been  
24 obtained and cared for up to the time it was found and  
25 then eventually assayed. So I thought that there was





Kauffman  
dr.ex. (Cronk)

H12 1 a possibility with all of that uncertainty that the  
2 concentration might at least in part be accounted for  
3 by artefact induced by the storage conditions.

5 One major artefact if it had been  
6 stored open for a period of months, or even in the  
7 refrigerator, is the possibility of evaporation  
8 which would reduce the volume of the sample if that  
9 occurred, and have the effect of artefactually  
increasing the concentration of digoxin in the sample.  
10 So I had to take that into consideration, that  
11 possibility, when I evaluated that number.

12 Q. And, doctor, we see from your  
13 comments to Mr. Wiley that you assumed that the  
14 actual concentration at the time of death of Kristin  
15 Inwood could well have been one-tenth the measured  
16 concentration in the frozen sample. I stop for a  
17 moment. Was that assumption a result, doctor, of the  
18 concerns that you had regarding both the purity and  
the nature of the storing of the sample?

19 A. Yes, that is correct. I was  
20 trying to determine in my own mind what the least  
21 the concentration might have been when the sample was  
22 fresh. And that is why I used an extreme number of  
23 one-tenth, to say even if we assumed an increased,  
extreme amount of evaporation, what would the

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H13 1 concentration still be?

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3 Q. Were you attempting, doctor,  
4 to assume then the worst conditions that might have  
5 applied, the worst effect that might have resulted  
6 because of the conditions of storage?

7 A. That was my idea, yes.  
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2 Q. And taking, Doctor, then a  
3 tenfold amount as the likely or possible in which you  
4 thought it to be, likely or possible level at the  
5 time of death, what conclusions did you reach regard-  
6 ing the implications of that concentration?

7 A. Making that assumption I assumed  
8 a situation where the concentration might have been  
9 a tenth of that which would be 49 micrograms per  
10 millilitre, and I thought this was still a high  
11 concentration and could have been associated with  
12 digoxin, a contribution of digoxin to the infant's  
death.

13 Q. That would make it, Doctor,  
14 on the pure mathematics, approximately 49 nanograms  
15 at the time of death.

16 A. That is right.

17 Q. Are you in any position on  
18 the information available to you, Doctor, to express  
19 in your opinion as to the likelihood that that was  
20 in fact close to the quantitative level at the time  
of death?

21 A. I think - my opinion is that  
22 that would be approximately - that would approximate  
23 the least it might have been.

24 Q. Doctor, on the basis of





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2 the information that was available to you were you  
3 as well able in this case to make any estimates  
4 regarding the possible time and route of administra-  
5 tion and likely dose of digoxin that may have been  
6 administered to the child?

7 A. Pardon me. I just want to  
8 review my notes before I answer you.

9 My feeling was that assuming this  
10 was a very high serum concentration, I didn't think  
11 it was actually 491 because I couldn't reconcile  
12 that with any type of feasible dose but I thought it  
13 was probably quite high. But assuming that I had  
14 to assume, and also based on the unusually high  
15 concentration in the fixed tissues even for fixed  
16 tissues, and the hypokalemia, if I accepted that as  
17 being related to digoxin intoxication rather than the  
18 doses alone, I felt that that composite picture  
19 suggested not only a large dose but probably within  
an hour or two prior to death, or terminal event,  
with relatively little tissue distribution.

20 Now that is referring primarily to  
21 the serum concentration. If you are going to explain  
22 a very high serum concentration like that you have to  
23 say to administer it in a feasible volume, a mechani-  
24 cally feasible volume, you would have to give it and

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2 have relatively very little distribution prior to the  
3 serum sample being obtained.

4 On the other hand what bothered me  
5 about that was the relatively high tissue concentra-  
6 tions for fixed tissues. If I took that into account  
7 I had to consider a rather high dose with some degree  
8 of equilibration of the tissues which set the time  
9 back a little further from death than what I would  
10 posit with the serum concentration alone, and I  
11 really couldn't be more specific than that because  
12 there just wasn't enough information to tie it down  
any more closely.

13 Now really I think if we accepted the  
14 tissue concentration was compatible with some distri-  
15 bution and viewing the relatively high serum concentra-  
16 tion, regardless of what dilutional factors you want  
17 to put on, I think we have to propose the dose if  
18 digoxin was given being given some time prior to an  
19 hour before death and maybe even longer than that,  
20 but again if a very large dose was given the infant  
21 might not survive for a number of hours with a very  
22 large dose so that that limits your outside figure to  
some degree.

23 Q. Doctor, if you hypothesize  
24 the most likely possibility a dose given approximately

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I.4 an hour or thereabouts prior to I take it the child's  
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agonal symptoms, critical symptoms?

A. Well, we are dealing with I suppose you could define it that way or the time that the child was finally pronounced dead. It is hard to define death in these children because many times they were in the process of dying over a period of 30 minutes to several hours. So I can't really tie it down real tightly.

I would say it was at least an hour before tissue distributions ceased which would be when cardiac output fell to such a low level the tissues weren't being profused any more or some time prior to that.

Q. Does that then, Doctor, necessarily rule out in your judgment the possibility of oral administration?

A. It doesn't totally rule it out, no.

Q. Well assuming, Doctor, --

A. I think it is unlikely because of the size of the dose that would have to be given to produce this total picture.

Q. Given what you have told us, Doctor, about absorption rates and the time necessary





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with an oral dose for distribution to in fact take place from the tissues, - from the serum to the tissues, is it in your view remote, a remote possibility that that was the method of administration, or is it a good candidate?

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A. No, I think it is a much more remote possibility than intravenous administration.

9

Q. Doctor, one of the matters raised by Dr. Spielberg with respect to this child had to do with the sequence of events that are recorded in the medical record as having occurred.

12

Do you have Exhibit 113 there, Doctor?

13

A. Yes.

14

Q. I would ask you to turn to page 63 if you would, please.

15

Do you have that, Doctor?

16

A. Yes, I have page 63.

17

Q. Doctor, the progress note on that page indicates that the child was given a dose of Lasix at approximately 11:10 p.m. on the evening of March 12th after which she is recorded to have voided urine. And then at 2:00 p.m. in the morning it is indicated that the monitor strip showed abnormalities, that the team leader, the nursing team leader was notified, a resident was called, Lasix

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2 in the amount of 3 milligrams was given IV by the  
3 resident once he arrived; tachycardia resulted,  
4 200 beats. The baby came I take to be very irritable  
5 and at 2:30 a Code 25 was called and the child was  
6 not able to be revived.

7 Dr. Spielberg has testified, Doctor,  
8 that given those, the recorded sequence of those  
9 events, that it is possible that digoxin either  
10 deliberately or accidentally was administered to  
11 this child in lieu of Lasix some time between 2:00 and  
12 2:30 in the morning. That is prior to the calling  
13 of the Code 25.

14 Is the possibility of a medication  
15 error with this child a matter, Doctor, that you  
16 considered in preparing your reports?

17 A. Yes, it was. In fact that  
18 had to be considered in virtually each of the cases.

19 Q. Assuming then, Doctor, that  
20 a dose of digoxin in the amount of 3 milligrams, the  
21 amount intended to be given for Lasix, assuming that  
22 that amount of digoxin was given between 2:00 and  
23 2:30, and that the child actually died some time after  
24 2:30 a.m., could a dose in that amount given within  
25 that time frame in your judgment account both for  
the post mortem serum level found and the concentration





I.7

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2 in this child's fixed tissues?

3

4 A. You are talking about the 2:00  
to 2:30 a.m.?

5

Q. I am.

6

A. Not the 11:10?

7

Q. No, I'm talking about the  
2:00/2:30 time frame.

8

A. I don't think so. I should  
do some arithmetic for you before I answer that  
definitively.

11

12 I think time-wise it doesn't fit the  
picture for me. I have a hard time reconciling that  
13 time frame with the tissue distribution.

14

15 There may be another problem here in  
terms of the size of the dose of digoxin that might  
16 have been given assuming this volume.

17

18 If you don't mind I'll do some  
arithmetic.

19

Q. No, please, Doctor. I think  
the matter is of some importance.

20

21 A. I think we have got 3 milligrams  
of Lasix was what the child was being given, and that  
22 would be 0.3 millilitres, so we have to see how much  
23 digoxin if the error was made, how much digoxin would  
24 be contained in three-tenths of a millilitre.

25





I.8

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2 If we assume the most that it would  
3 contain, that would be the adult intravenous prepara-  
4 tion, so that would have contained .25 milligrams per  
5 ml in the adult preparation. So if we divide - well,  
6 it would be three-tenths of this. That would be  
7 .075 milligrams.

8 So if that error was made and if the  
9 appropriate volume - the error simply was that the  
10 wrong medication was drawn out but the appropriate  
11 volume, this is the amount of digoxin that would be  
12 contained in that. Then we need to look and see what  
this baby weighed. I think it was  $2\frac{1}{2}$  --

13 Q.  $2\frac{1}{2}$  kilos.

14 A.  $2\frac{1}{2}$  kilos. So let's assume -  
15 in this situation we are talking very little,  
16 essentially no distribution because the dose was  
17 given shortly before death, so we will assume a small  
18 volume of central compartment volume distribution to  
the tissues. It would be 1 litre, approximately  
19 1 litre per kilogram which would be 2.5 litres, and  
20 if we put this amount of digoxin into this volume  
21 we will get - that would give us a concentration of  
22 30 nanograms per ml at the most.

23 So I don't think - this doesn't fit  
24 the picture very well for several reasons: one is  
25





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it doesn't account for any digoxin in the tissues,  
and secondly it doesn't account for the post mortem  
serum concentration.

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Q. Then can we deal with the  
latter issue first, Doctor? If we assume that this  
kind of an error was made, achieving a concentration  
that you have calculated to be 30 nanograms at the  
most per millilitre, if we take into account first of  
all a multiplier within a range that is acceptable to  
you, and if we, for example, suggest that the multi-  
plier in this case was 3 or 4, taking the outside  
4, that level could elevate in known ranges to  
120 nanograms post mortem. Would that be correct?

14

A. That is possible.

15

16

17

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21

Q. And if we take then, Doctor,  
further into account the possible effect of  
dessication or evaporation or a contaminant in the  
sample as you did in considering the 491 nanograms,  
is it not also possible that further elevation from  
120 could be fully accounted for by the storage  
conditions that applied or could have applied with  
respect to that sample?

22

A. Yes, I think that is possible

23

Q. That we could go from 120 to

491 by virtue of those conditions?

24

25





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A. If we look at serum itself

I think we could fit it to this scenario of an error  
like this.

5

6

My problem is I have a hard time

reconciling it with the tissue concentrations.

7

Q. Right. As I understood it,  
Doctor, the assumption you made in doing these  
calculations was that it was a central compartment  
calculation, very little distribution time from the  
serum into the tissues; is that correct?

11

A. That is correct.

12

13

14

15

Q. All right. Doctor, assuming  
again that the concentration was 30 nanograms per  
millilitre, is that amount consonant with what you  
understand to be a therapeutic dose of digoxin, a  
maintenance dose?

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BB/cr

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A. Dose or concentration?

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Q. I am sorry, the dose that  
you estimated - well, the volume of digoxin you  
described was .075 milligrams.

3

A. That's the dose.

4

Q. That's the amount of the  
digoxin?

5

A. That's the amount of the  
digoxin.

6

Q. Is that amount consonant  
with what you would consider to be a maintenance  
dose of digoxin?

7

A. Not a maintenance dose, no.

8

It would be about three times a maintenance dose.

9

Q. Thank you, Doctor. One  
final matter with respect to Kristin Inwood, Doctor.  
There has been evidence led before the Commission  
suggesting that this child in fact received a dose  
of digoxin prior to her death that was intended for  
another patient, a medication error in fact was made. She  
received in that regard - I am not sure that I have  
the amount at hand - but the incident took place,  
Doctor, at 5:30 a.m. on the 12th of March and it  
resulted in a digoxin level of 2.6 nanograms at  
9:00 a.m. that day.

10

11





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THE COMMISSIONER: That's the amount  
intended for some other child, I think it was the  
Pacsai child.

3

4

MS. CRONK: I think that is correct,  
Mr. Commissioner.

5

6

THE COMMISSIONER: So, we can easily  
discover the amount if you want to have it by looking  
at the Pacsai chart.

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MS. CRONK: Q. Well, it may be  
relevant for you, Doctor. My question on this matter,  
sir, is simply this. Having regard to the fact that  
we know and have a concrete example that at least  
one medication error took place with Kristin Inwood,  
does that affect your views as to the likelihood that  
another could have occurred in exactly the same way  
that you have outlined it here so as to account  
for the levels that were seen in her blood post  
mortem?

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A. I can't really say that one  
medication error changes the probability of another  
medication error. I think that the probabilities  
of medication errors, of individual medication  
errors are probably independent, the probabilities  
are independent of each other, so, I can't really  
say that the fact that a medication error occurred





1

2 earlier would make it more or less likely that  
3 another medication error would have occurred later.

4

5 Q. Doctor, the amount that she  
6 received in error was apparently .02 milligrams, is  
7 that correct?

8

9 DR. GILMOUR-BRYSON: I think it is  
10 .032 if it is Pacsai.

11

12 MS. CRONK: Q. I am sorry, I will  
13 have to check that and give it to you later in the  
14 day.

15

16 A. That seems like a very large  
17 dose.

18

19 Q. In any event, Doctor, I  
20 suggest to you that we know that the digoxin level  
21 which resulted following the administration of that  
22 dose was the 2.6 nanograms level reported at 9:00 a.m.  
23 Would you agree with me that if that were the level  
24 resulting from that medication error that it is  
25 unlikely that an excessive dose was given at that  
time to the child?

26

27 A. Yes, I think it is unlikely.  
28 It may have been a little - I think that Kevin  
29 Pacsai weighed more than Kristin Inwood so that the  
30 dose might have been larger than a usual maintenance  
31 dose for Inwood but I don't think it resulted in a  
32

33





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2 serum concentration that would be associated with  
3 toxicity. If I have the times correct, I wasn't  
4 aware when I did this report of this medication  
5 error but if I have the times correct that you have  
6 just given me I think that that is about three to  
7 four hours after the error that that level was drawn.

8

Q. That is correct, Doctor.

9

A. So that I would expect that  
10 that would be maybe even a little higher than the  
11 steady state level after distribution took place.  
12 So, I suspect the level was somewhere - this probably  
13 represents the most the concentration serum would  
14 have been resulting from that error.

15

Q. Thank you, Doctor. Doctor,  
16 I will check the amount of the dose precisely and  
17 provide that information to you.

18

A. Okay.

19

Q. Aside from Kristin Inwood,  
20 Doctor, there are two other children dealt with in  
21 your original reporting letter to Mr. Wiley: they  
22 are John Onofre and Laura Woodcock dealt with  
23 respectively at pages 11 and 12 of your first  
24 reporting letter.

25

As I understand it in neither of  
those cases was there in your judgment sufficient





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2 evidence or data available to you to allow you to  
3 assess the involvement of digoxin intoxication, is  
4 that correct?

5 A. That is correct.

6 Q. Right Doctor, there is  
7 one additional area that I would like to discuss with  
8 you today if I may. As I understand it, in addition  
9 to the reporting letters which you prepared for Mr.  
10 Wiley you were as well requested to serve as a  
11 consultant in pharmacology to the authors of what  
12 has been described here at the Atlanta Report, that  
13 is, the report produced by the Centers for Disease  
14 Control in Atlanta, is that correct?

15 A. That is correct.

16 Q. Doctor, can you tell me how  
17 and when that came about?

18 A. Would you excuse me a moment  
19 I will get my information, notes from that and I can  
20 answer you more specifically. Some time I think  
21 during the month of October, but it may have been as  
22 early as September, but some time I had consented  
23 to be a consultant for the Crown Attorney I was  
24 consulted by Doctor - it slips my mind now - from  
25 the CDC - Clark Heath and also by Dr. L.  
Smith from the Ontario Ministry of Health asking





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me if I would agree to be a consultant to the work  
that they were doing in relation to these deaths.  
I told them at the time that I had already agreed  
to be a consultant to the Crown Attorney and that  
I would like them to make sure that it was okay to  
serve as a consultant to both groups simultaneously  
before I would agree to do that.

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me if I would agree to be a consultant to the work  
that they were doing in relation to these deaths.  
I told them at the time that I had already agreed  
to be a consultant to the Crown Attorney and that  
I would like them to make sure that it was okay to  
serve as a consultant to both groups simultaneously  
before I would agree to do that.

She subsequently - they subsequently -

I say she because the letter I have here is from Dr.  
Smith. I have a record that she told me late in  
October that she had spoken to the police and the  
Crown Attorney and that they had no objection to me  
working simultaneously to provide consultation to  
them, being the police and a joint consultation to  
the Epidemiology Study Team.

So, following that, I did agree to  
simultaneously serve as a consultant to both groups.

I did make it very clear to them that I would not  
share, I would not myself share information provided  
by one party with the other party in terms of  
specific information. Obviously I was aware of  
information from one party that may not have been  
available to the other party and I took that  
information into consideration when I made judgments  
but I did not share specific information one with





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7 the other. I told them that if they cared to share  
2 information then they would do it themselves but I  
3 would not share that. So, I kept the files separate  
4 except if I was doing work that related to both  
5 consultations I of course had all the information  
6 that I had available to me out at that time.

7

8 Q. Doctor, what specifically  
9 were you asked to do by Drs. Heath and Smith?

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A. The general request was to assist them from a pharmacological point of view in their epidemiologic study of the deaths at the Hospital for Sick Children. Eventually that boiled down to a specific request and that was to review the charts of, I believe 37 infants, and I was asked to attempt to rank, or not rank, but rate each case in terms of a numerical probability value, rate them as to the probability that digoxin had contributed to their death. I was asked to do this primarily with respect to pharmacologic data but also take into consideration all other data including clinical data on the chart. Other consultants were looking solely at clinical information.

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Q. Doctor, at the time that this request was made of you and you ultimately accepted the assignment, had you at that point, for the





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2 purposes of the review requested by Mr. Wiley,  
3 already reviewed the medical records of the some  
4 36 children about which we are concerned?

5 A. I had not reviewed the  
6 medical records themselves at the time I consented  
7 to consult with the CDC. I had reviewed summaries  
8 and forensic data but I had not yet reviewed the  
9 actual medical records at the time I agreed to  
consult with the CDC.

10 Q. Did you do it then on two  
11 separate occasions; once for the purposes of the  
12 review for the Crown Attorneys and on a second  
13 occasion for the purposes of review for the Atlanta  
14 group?

15 A. No, my review of the actual  
16 medical records was done on one occasion for both  
17 purposes. Actually, what happened, was I came to  
18 Toronto after I agreed to be a consultant for both  
19 parties. I came to Toronto and I spent approximately  
20 12 hours one day in a windowless room in the Hospital  
21 with all the original records in the room with me  
22 and all my other information from all other sources  
23 and I sat there alone all day and looked at each  
individual case, the original record as well as all  
the other information I had on that case and filled

24

25





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2 out the scoring sheets one by one with the information  
3 with me at that time.

4 Q. All right. Are you saying  
5 then, Doctor, that the ratings that you did for the  
6 purposes of the Atlanta CDC group were done at the  
7 time that you physically reviewed the medical record  
of each child?

8 A. That is correct.

9 Q. All right. Doctor, was  
10 anything provided to you in writing either by Drs.  
11 Heath or Smith or any other individual connected with  
12 the CDC group by way of written terms of reference  
as to what you were being asked to do?

13 A. I would have to review all  
14 my correspondence to answer that specifically but I  
15 can answer it generally. At the time I did this the  
16 specific terms of reference were primarily the  
17 scoring sheets that I filled out. They essentially  
18 incorporated the specific terms of reference.

19 Q. All right. Well, I will come  
20 in a moment to the specific scoring sheets, Doctor.

21 A. Fine. At the time I did this  
22 I was aware of their general approach. I was aware  
23 that they were doing an epidemiologic study of the  
24 deaths. I was not aware at the time I completed the  
25





1  
2 scoring sheets as to how they were going to use that  
3 data in their study and there was no reason why I  
4 should be aware of that. I didn't care to be aware  
5 of it because I wanted to be as unbiased as I could.  
6 So, in that sense I was blinded when I did it but I  
7 was not blinded in the sense that I knew which patients  
8 I was dealing with when I scored them. But I did not  
9 know at the time that I filled them out how that data  
10 was eventually going to be used in the entire context  
11 of the whole study.

12 Q. Fine. Doctor, you have  
13 mentioned some scoring sheets. Can you tell me  
14 whether you designed and settled the contents of  
15 the scoring sheets or were they provided to you?

16 A. I didn't design them. I  
17 approved them after they were designed and said I  
18 thought they were okay and then they were provided to  
19 me by the CDC staff.

20 Q. All right. Doctor, who  
21 determined the criteria upon which each of these cases  
22 were to be rated?  
23  
24 - - -  
25



DM.jc  
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A. I think that after I had the scoring sheets then I sat down and I outlined the criteria that I thought I could use to try to separate cases into 5 categories of probability. Had I known when I designed the criteria what I knew after I filled out the sheets I might have done it differently, but that wasn't the way I wanted to do it.

What I was being asked to do actually was to assign a numerical value to an opinion of probability so that they could put numbers into the computer. Unfortunately as I got into it there were some cases that didn't fit my cubbyholes as nicely as I would have liked them to, and so I had to make a somewhat subjective decision on some cases as to which category I would eventually put them into based on my best judgment at the time I was looking at the chart. But I designed the criteria that I then used to put the numerical rating on each case.

Q. Doctor, we have heard that Dr. Alexander Nadas, chief emeritus of cardiology at the Children's Medical Center in Boston, served as a consultant cardiologist to the CDC group, if I may refer to it that way. Did you, Doctor, before rating these cases for the CDC group have the benefit of Dr. Nadas' views with respect to any of these cases





K.2

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2 be it orally or in writing?

3 A. No, we never had any communica-  
4 tion in any way shape or form, and I don't even know  
5 when he did his actual evaluations in the cases, we  
6 were never there at the same time, we never had any  
7 correspondence, we never talked to each other, we  
8 did our evaluations totally independently.

9 Q. Similarly, Doctor, we have  
10 heard Dr. Derek DeSa, Chief of Pathology at Winnipeg  
11 Children's Hospital, served as a consultant pathologist  
12 to the CDC group. Once again, prior to rating these  
13 deaths for the CDC group, and completing your work  
14 for them, had you discussed any of these cases in  
15 writing or orally with Dr. DeSa?

16 A. No, we never saw each other,  
17 or communicated in any way. We don't even know each  
18 other.

19 Q. Doctor, to be perfectly clear  
20 about the matter you outlined, what may seem many days  
21 ago but was in fact a day and a half ago, for us, the  
22 nature of the information that was available to you  
23 when you started your review for Mr. Wiley. You  
24 referred for example to summaries, case summaries  
25 prepared by Dr. Hastreiter; the toxicology data from  
Mr. Cimbura, to name but a few. Do I have it correctly





K.3

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2 that when you did these ratings for the CDC group you  
3 had available to you for your personal use all of  
4 that information that had been provided, either  
5 through the Metropolitan Toronto Police, Mr. Cimbura  
6 or the Crown Attorney's office?

7

A. I had everything that had been  
7 provided to me up to the date that I did the  
8 evaluations, yes.

9

Q. Well, can you help me, Doctor,  
10 as best you can recall, what the date was when you  
11 actually did the ratings for the CDC group?

12

A. I can look it up if you will  
12 give me a moment.

13

Q. If you would, please.

14

A. My records indicate that I did  
15 the on-sight review of the charts on November 19th,  
16 1982.

17

Q. Would I be correct then,  
18 Doctor, in assuming that the information which was  
19 provided to you subsequent to the date of your  
20 delivery of your first reporting letter to Mr. Wiley,  
21 and we have seen several examples of that, for  
22 example the post mortem serum level in Kristin Inwood,  
23 the gutter blood study information on Janice Estrella,  
24 information of that type, was not available to you

25





K.4

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2 nor known by you at the time that you did these  
3 ratings for the CDC group?

4

A. That is correct.

5

6 Q. Doctor, you have told us that  
7 you personally designed the criteria by which these  
8 cases were to be rated. You have told us that the  
9 scoring sheets were provided and ultimately, were  
provided to you by the CDC group and ultimately  
approved by you.

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I have provided to you what I understand to be a bound version of your completed scoring sheets of these children, together with a copy in blank of what I understand to be the scoring form provided by the CDC group; and as well a copy of what I understand to be the criteria employed by you. Do you have that volume with you?

A. Yes, I do.

Q. Mr. Commissioner, these

materials have been provided to all other counsel but regrettably there was insufficient time to bind them in the same way for them, but they have been provided with the coding key in order that the identity of the involved child might be recognized. Doctor, I would ask you first if you would --

THE COMMISSIONER: They key, oh yes, all right.





K.5

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2 MS. CRONK: Q. Doctor, I would ask you  
3 first if you would to turn to Tab 1 of our volume.

4 THE COMMISSIONER: Could we just  
5 before we forget, we almost forgot the last one,  
6 could we make this Exhibit 272.

7

MS. CRONK: 272, sir?

8

THE COMMISSIONER: Is that right?

9

MS. CRONK: For the benefit of other  
10 counsel then, sir, to make it clear, that exhibit then  
11 includes what I will be discussing in a moment with  
12 Dr. Kauffman, a letter dated December 14, 1982 from  
13 Dr. Kauffman to Dr. Smith. It includes in blank a  
14 form of scoring sheet. It includes the completed  
15 scoring sheets on 36 of the 37 children that  
16 Dr. Kauffman reviewed for the CDC group, the 36 being  
17 the 36 with whom this Commission is concerned.

18

--- EXHIBIT NO. 272: Letter dated December 14, 1982  
19 from Dr. Kauffman to Dr. Smith;  
20 Blank Form of Scoring Sheet;  
21 Completed Scoring Sheets on  
22 36 children.

23

THE COMMISSIONER: What is the 37th?

24

25

MS. CRONK: The 37th, sir, as I under-  
stand it, was a patient by the name of Gittens who  
did not die within the time frame with which we are  
concerned on these wards, the child's name was Gittens.

THE COMMISSIONER: Yes, all right.





K.6

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2 MS. CRONK: Q. Doctor, can I ask you  
3 first then to turn to Tab 1 of our volumes, which is  
4 the letter dated December 14, 1982 to which I have  
5 referred, which appears to be a letter from you  
6 directed to Dr. Smith of the Ontario Ministry of Health.

7

8 Doctor, I take it that this was a  
9 letter that you sent to Dr. Smith?

10

A. Yes, it is.

11

12 Q. And Doctor, as I read the  
13 letter, in the first two full pages you are outlining  
14 essentially a number of concerns or comments that you  
15 had as to the difficulties of interpretation that  
16 arise with various digoxin levels and concentrations  
17 in various types of specimens, including ante mortem  
18 and post mortem blood specimens; fresh and frozen  
19 tissue specimens; fixed tissue specimens; and exhumed  
20 tissue specimens; do I have that correctly?

21

A. That is correct.

22

23 Q. Doctor, are the comments  
24 outlined on the first two pages of this letter in  
25 substance identical to the comments that you made on  
the same interpretive problems in your first reporting  
letter to Mr. Wiley that we have earlier reviewed?

26

A. That is correct.

27

28 Q. Doctor, if we turn to page 3

29

30





K.7

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2 of your letter, if you would, please, are the criteria  
3 which you used to rate these 36 children in terms  
4 of the probability of death resulting from digoxin  
5 intoxication outlined in full on that page?

6

A. Yes, they are.

7

Q. And may I have it again for  
8 absolute clarity, Doctor, these were criterias as I  
9 understand your evidence, designed and selected by you  
10 to permit you to rate in terms of probability these  
deaths?

11

A. That is correct.

12

Q. And in terms of probable  
13 involvement of the drug digoxin intoxication, Doctor,  
I take it your highest rating was a 5?

14

A. That is correct.

15

Q. And deaths rated --

16

A. Pardon me, I was instructed by  
17 the CDC because of the design of the rating sheets  
that 5 was high and 1 was the low end.

18

Q. All right.

19

A. So that was within the design  
20 of the rating sheets, that was a given.

21

Q. You anticipate my questions,  
22 Doctor, because others might have approached the  
23 numerical sequence a little differently. Do I have

24

25





K.8

1  
2 it correctly then that those cases where you considered  
3 the probability of death resulting from digoxin  
4 intoxication to be most probable were rated with a 5?

5 A. That is correct.

6 Q. And conversely, those cases  
7 where you felt it least probable that death had  
8 resulted from digoxin intoxication were rated with a 1?

9 A. That is correct.

10 Q. Obviously, Doctor, there are  
11 without showing any particular brilliance at this  
12 time of the day, Doctor, three ratings within those  
13 two extremes. May we fairly infer from the ratings  
14 which you have outlined on page 3 of this letter that  
15 any death with the rating of 3 or more in your judgment  
16 was a case where there was a reasonable probability  
17 that death had resulted from digoxin intoxication?

18 A. There was certainly a  
19 possibility, and I suppose you could call it a  
20 reasonable probability, yes.

21 Q. 3 or more?

22 A. 3 or more. I would certainly  
23 agree that those with ratings 2 and 1 I really  
24 considered a very low probability, and I am not sure  
25 that realistically I can differentiate between 2 and 1,  
but I had to use up the numbers.





K.9

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Q. Thank you, Doctor. Doctor, I  
don't intend to review in detail with you the various  
criteria that you used, they are set out in full. May  
I with respect to Rating No. 5 draw your attention  
first to the rating - I am sorry, the introduction to  
the rating category. You have indicated that patients  
receiving a rating of 5 had to meet at least 4  
of the following criteria?

A. That is correct.

Q. Do I take it from that doctor  
that it could be any 4 of the 5 outlined but it had  
to be 4?

A. Any 4, but 4.

Q. And Doctor, if I can draw your  
attention to Criteria No. 5, under Rating No. 5 you  
indicate:

"No digoxin prescribed at time of  
death."

Does that necessarily limit the  
patients potentially within this rating as being those  
for whom no digoxin was known to have been prescribed  
during life, or is it at the time of death?

A. I unfortunately didn't say  
what I meant and what I did. What I meant was no  
digoxin prescribed during life.





K.10

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2 Q. And is that what you did?

3

A. That is what I did, yes.

4

5 Q. And Doctor, with respect to  
those patients rated with a rating of 4, do I take it  
that all 3 criteria outlined had to be met?

6

A. That is correct.

7

8 Q. And similarly, Doctor, with  
Rating 3, do I take it that for any patient to fall  
9 within that category both criteria had to be met?

10

A. That is correct.

11

Q. And there is only 2?

12

A. That is right.

13

14 Q. And for Rating 2, Doctor, in  
that category, any patient rated with that rating had  
15 to have at least 2 of 3 criteria which you have  
outlined?

16

A. Right.

17

Q. But it could be any 2 of the 3?

18

A. Any 2 of the 3.

19

20 Q. And Doctor, when we move to the  
last group, the Rating 1, once again you have set out  
21 3 criteria. Do I have it correctly that a patient  
rated with a 1 had to have at least 1 of the 3?

22

A. That is correct.

23

Q. But could have only 1?

24

25





K.11

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2 A. That is correct also.

3

Q. So in some instances the

4

particular patient could have satisfied all 3 criteria  
but that is not necessarily the case?

5

A. That is right.

6

Q. Doctor, may we turn then next  
7 if you would to Tab 2 of our volume, which for the  
8 benefit of other counsel is what I understand to be  
9 the blank scoring sheet, or at least a sample of a  
10 blank scoring sheet provided to you by the CDC group.

11 Is that what this document represents, Doctor?

12

A. Yes, it does.

13

Q. And Doctor, if we can go first  
14 to page 1 of the scoring sheet; we see there Doctor -  
15 well, I am sorry, to be perfectly clear there are a  
16 number of questions set out on the coding sheet. The  
first is:

17

"Was death the result of digoxin  
18 intoxication?"

19

And the instructions appear, circle 1, least  
20 probable is assigned the number 1; most probable the  
21 number 5. Do I have it correctly that your probability  
22 rankings would thus be recorded numerically on the  
right-hand side of this scoring sheet?

23

A. I honestly don't recall if I

24

25





K.12

1

2        circled them and then a staff person wrote in in  
3        the right-hand column, or if I wrote the numbers in  
4        the right-hand column, I don't remember.

5 Q. I put the question - you have  
6 answered the question I posed, Doctor, but the question  
7 was put badly, I am less concerned with the mechanics  
8 of it than the fact that I take it if the child was  
9 rated by you with a 2 you would simply answer the  
question by circling the 2?

A. That is correct.

13 A That is correct.

16 "This assessment is based on the  
17 following types of data".

The instructions are to circle 1 or more, and then  
there is a resuscitation of 5 particular types of  
data which potentially might be available in the  
Category 6 for any other data that might be available.  
On the right-hand side in writing, Doctor, we see an  
indication that the codes will be: 1 equals no; or  
2 equals yes, do you see that?

24

25





K.13

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A. Yes.

3

4

5

6

7

Q. Do I correctly have it, Doctor, then, for example, that if one of the types of data you were relying on were the pre mortem blood specimen you would insert the number 2 in the right-hand column indicating yes, there was that type of data that you had reference to?

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30nov83  
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EMTra

A. What I actually did I circled  
whichever data I listed, and somebody else later did  
the digital coding.

3

4  
Q. All right.

5

6  
A. I didn't want to get confused  
by the ones and twos so I just circled them.

7

8  
Q. And you circled the ones then  
indicating the type of data that was in fact available?

9

A. That is correct.

10

11  
12  
13  
14  
15  
There could be some confusion as to  
how I indicated these. The fact that I may have  
circled data or not circled -- well let me say it this  
way: The fact that I may have not circled a particular  
piece or type of data does not necessarily mean it  
wasn't available. It means I didn't use it in my --  
I didn't consider it in my decision.

16

Q. All right.

17

18  
19  
20  
A. If I did circle it it meant it  
was available and I did use it, take it into considera-  
tion in my decision, and if there was something that  
I considered which was not listed I simply wrote it  
under "other".

21

22  
23  
Q. Do I take it then, doctor, if  
you circled a particular type of information it meant  
two things: First, that it existed, and secondly that

24

25





1

L2 2 you had relied upon it?

3

A. That is right.

4

5

6

7

And the fact that I used it had no

implication as to how I used it. In other words, the  
fact that I circled it doesn't mean that there was  
abnormal data of that type; it may have been normal or  
abnormal data of that type.

8

Q. I see, doctor. And when we  
9 come to the particular cases perhaps you can provide  
10 some illustrations to us as to the kind of variability  
11 that you are discussing.

12

13

14

15

May we turn then to the third

question on page 2 of the blank coding sheet. That  
question is described as: "Did digoxin intoxication  
appear to be the result of...", and then there are  
five potential answers to the question.

16

17

You are instructed to circle one or

more as you felt to be applicable.

18

19

20

Do I have it correctly, doctor, that

that question was really directed to your opinion as  
to the cause of digoxin intoxication where you felt  
that it in fact existed?

21

22

23

24

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A. When I felt that there was a

reasonable probability that it existed then at that  
moment that I was doing this indicated my impression of





1

L3 2 how it could have occurred. If indeed it did.

3 If I felt that it was -- well, if I  
4 didn't feel that there was a likelihood of digoxin  
5 intoxication I indicated that it wasn't applicable.

6 If I thought that there was just no  
7 way at all that I could speculate as to the mode of  
8 administration then I circled "unable to determine".

9 In most cases even thought it might  
10 have been highly speculative I tried to give some  
11 impression of how I thought it could have been  
12 administered. Because at the time I had no idea how  
13 this was going to be used and so I was trying to give  
14 as much information as I could or judgment kinds of  
15 data even though it might have been fairly speculative.

16 Q. And, doctor, the next question  
17 I think is perhaps self-explanatory. It reads: "Are  
18 there other medications which may have contributed  
19 to terminal events?"

20 There are various potential responses  
21 outlined. The first is a negative, the second is  
22 affirmative, "Yes"; the third is "unable to determine"  
23 and the last is "not applicable".

24 Do I have it correctly that if you  
25 felt that there was a medication which might have  
26 contributed to the terminal events of any particular





Kauffman  
dr.ex. (Cronk)

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L4 2 patient you would circle the "yes"?

3 A. That is correct.

4 Q. Similarly if you felt there were  
5 none you would indicate that by circling the "no"?

6 A. Either if I felt there was not  
7 or I had no evidence that there were.

8 Q. All right. And in situations  
9 where it was a question mark in your mind I take it  
you would circle "unable to determine"?

10 A. That is correct.

11 Q. And then a related question,  
12 doctor, is the following one: "Are there other  
13 medications which may have modified response to  
digoxin?"

14 Can you tell me first what you  
15 understood that question to mean.

16 A. I primarily there was looking  
17 for drug interactions that might have either changed  
18 the concentrations of digoxin or the elimination of  
19 digoxin or drug-drug interactions which may have  
20 affected or changed the effect of digoxin on the  
patient.

21 Q. And if you felt that there was  
22 a drug that might have done that you would indicate  
23 your answer by circling the affirmative?

24

25





Kauffman  
dr.ex. (Cronk)

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L5 2

A. That is correct.

3

4

5

6

Q. And similarly if you were unable to determine whether or not a particular drug or drugs had such an effect or interaction you would indicate that you were unable to determine?

7

A. That is correct.

8

9

Q. And the final category on the coding sheet, doctor, page 2, is entitled "Digoxin Earliest Time of Fatal Dose".

10

11

12

13

14

There is a space for a date to be inserted; a space for a time to be inserted, but there is a handwritten note that appears on the bottom of the page on the right which reads, "Note: This will be done only for six cases. All others won't have these lines on the form."

15

16

17

To the best of your understanding, doctor, were you to complete that information in the cases that you reviewed?

18

19

A. Frankly I don't recall putting that information on any of them.

20

21

22

23

24

25

Q. Thank you, doctor.

Doctor, if we turn to page 3, that page is largely in blank, but the heading is: "Comment on likely route, dose, timing of administration".

Do I have it correctly that where it





1

L6 2 was possible for you to do so you would have completed  
3 this page in the scoring pages to indicate what you  
4 felt to be the most likely route of administration of  
5 digoxin, the most likely dose that was administered and  
6 the most likely timing of its administration?

7 A. That is essentially what I did.

8 What actually happened as I recall it  
9 is I used this plate, this area, to make pencilled  
10 informal notes, and I may have put down information  
11 at times that wasn't specifically directed towards  
12 these questions. But where I thought at that point in  
13 time that I could, I did make comments directly re-  
14 lated to these also.

15 Q. And, doctor, if we turn to  
16 page 4, that page simply provided for any other  
17 miscellaneous comments that you might have with  
18 respect to any particular patient?

19 A. That is right. Again these  
20 were informal pencil notes that I made after I filled  
21 out the other things. If I felt there were other  
22 things that I should note about a particular case.

23 Q. And, doctor, did the remainder  
24 of the documents contained in this volume represent  
25 your completed scoring cards on the 36 children with  
whom this Commission is concerned?





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L7

2 A. I haven't looked at each one  
3 of them but they appear to be that, yes.

4

MS. CRONK: All right.

5

Mr. Commissioner, I note the time.  
I would, however, make one suggestion with your  
concurrence. It is my intention to introduce through  
Dr. Kauffman a summary page of the results of his  
completed scorings for these children. I think it  
might be of benefit -- I am hoping it will be a  
benefit both to you, sir, and other counsel.

11

THE COMMISSIONER: Yes.

12

MS. CRONK: With your indulgence  
for another five minutes I believe I could do that  
before the luncheon break. If you prefer not to I  
could do it first thing after lunch.

15

THE COMMISSIONER: No, I would be  
delighted. But where would that leave us?

17

MS. CRONK: That will leave me about  
fifteen minutes from sitting down, sir.

19

THE COMMISSIONER: Yes. All right.  
I think probably it would be helpful if we got the  
summary now.

21

MS. CRONK: I think so too, sir.

22

Q. Dr. Kauffman, I am showing to  
you a summary sheet entitled "Ratings by Dr. Ralph

24

25





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2 Kauffman". I previously provided a copy of this to  
3 you, doctor.

4 It is divided into two headings.

5 On the left-hand side of the page, "Re: Probablity of  
6 Death as a Result of Digoxin Intoxication" and on  
7 the right-hand side of the page, "Re: Cause of  
8 Digoxin Intoxication".

9 Does the information set out in those  
10 two columns, doctor, accurately reflect, first, the  
11 particular probability ratings that you assigned to  
12 these 36 children? That is the information in the  
13 left-hand column. Does it accurately reflect the  
14 ratings that you gave, doctor?

15 A. Yes, I believe it does.

16 Q. And, doctor, the right-hand  
17 side of the page in the column entitled, "Ratings Re:  
18 Cause of Digoxin Intoxication", does the information  
19 set out beside each child's name in that column  
20 accurately represent your answer to Question No. 3 on  
21 the coding sheet? That is, your answer to the cause  
22 of digoxin intoxication where you thought it was  
23 reasonably probable that it existed.

24 A. Yes, I think it fairly  
25 represents that.

26 Q. All right. And, doctor, I am





1

2 showing you now --

3 THE COMMISSIONER: That should be  
4 Exhibit 273, I think.

5 --- EXHIBIT NO. 273: Document entitled, "Ratings  
by Dr. Ralph Kauffman".

6 MS. CRONK: Q. Doctor, I am showing  
7 to you another form of summary sheet entitled, "Summary  
8 of Children Rated by Dr. Ralph Kauffman with Ratings  
9 #5 to #2 Inclusive."

10 I would ask you, doctor, with  
11 reference to all of those cases where you assign a  
12 probability rating of 2 or greater, are those  
13 children accurately identified in the first column  
14 of this summary on the left?

15 A. I believe they are without  
16 double-checking it, but I believe think they are.

17 Q. Doctor, if we move then to  
18 the second column on the page, once again that  
19 information I suggest and would ask for your agree-  
20 ment, is a repetition of what the actual probability  
21 rating was that you assigned to each of these  
22 children?

23 A. Yes, I believe so.

24 Q. And the third column of  
25 information is repetition with respect to each child  
of what you felt to be the cause of the digoxin





1

2 intoxication?

3 A. I believe so.

4 Q. And the fourth column, doctor,  
5 I suggest contains the answer to your question in  
6 each of the ten case as to whether or not you felt  
7 other medications may have contributed to the child's  
terminal event?

8 A. Yes.

9 Q. And finally, doctor, the last  
10 column of information contains I suggest your answer  
11 to the question on the scoring sheet as to whether or  
12 not other medications may have modified the patient's  
13 response to digoxin?

14 A. Yes.

15 Q. And, doctor, I previously  
16 provided a copy of this summary to you as well to re-  
view?

17 A. Right.

18 MS. CRONK: May that be marked as  
19 the next exhibit?

20 THE COMMISSIONER: Exhibit 274.

21 --- EXHIBIT NO. 274: Document entitled, "Summary of  
22 Children Rated by Dr. Ralph  
23 Kauffman with Ratings #5 to  
24 #2 Inclusive".

25 MS. CRONK: May we take our break, sir,  
at this point?





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5884

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2 THE COMMISSIONER: All right.

3

We may be in trouble; we may be

4

sitting later tonight, I don't know, but we will see

5

where we stand at 4:30.

6

MS. CRONK: Thank you, sir.

7

---- luncheon recess.

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Kauffman, dr.ex.  
(Cronk)

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---Upon commencing at 2:30 p.m.

3

THE COMMISSIONER: Yes, Miss Cronk.

4

MS. CRONK: Good afternoon, sir.

5

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9

Q. Dr. Kauffman, before we broke for lunch I had introduced and we had marked two summary sheets. I would ask you to put Exhibit 273 before you which is the longer of the two. Do you have that, Doctor?

10

A. Yes.

11

12

13

14

Q. Doctor, reviewing the probability ratings which you assigned to the various children, I take it that there were seven cases where you assigned a rating of 3 or greater than 3 in terms of probability.

15

A. That is correct.

16

17

Q. And in addition to that there were three cases that you rated 2, that is, slightly more than the least probable category?

18

A. That is correct.

19

20

21

Q. Doctor, there were 26 children of our group of 36 where you felt a least probable rating was appropriate?

22

A. That is correct.

23

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Q. And if we look, Doctor, at the seven cases where your ratings were 3 or greater





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and turn to what your views were concerning the cause of digoxin intoxication, with the exception of two cases amongst those seven, you felt that it was most likely to be a single overdose, an acute event. Do I have that correctly?

A. That is correct.

Q. Can you briefly explain for us, Doctor, what you meant by that ranking for these five children?

A. At that time I think I was postulating the single dose and that it had been administered as a single dose some time obviously prior to the infant's death. I don't think that these terms implied any particular time frame.

Q. In terms of the timing of the administration of the dose?

A. That is correct.

Q. All right, merely the method.

A. The method.

Q. All right. Doctor, as I have said or suggested to you, there are two cases where you have indicated out of the seven cases that you were unable to determine the likely mode of administration, that is, Kristin Inwood and Jordan Hines. Do I have that correctly?

25





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AA3 A. That is correct.

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Q. All right. Doctor, I don't intend to take you in detail through all of these cases but there are one or two that I would like to look at with you. The only child amongst the entire group of 36 to whom you assigned a most probable rating was Justin Cook, is that correct?

9

A. That is correct.

10

11

12

13

Q. All right. Doctor, would you turn with me to Justin Cook's coding sheet which in your book is found at Tab 37. While we are doing that, Doctor, could you put the other summary sheet in front of you if you would, please.

14

A. Yes.

15

Q. It is Exhibit 274, sir, the other summary sheet.

16

THE COMMISSIONER: Yes, but what else are we to look at?

17

18

MS. CRONK: The coded sheets for Justin Cook at Tab 37.

19

THE COMMISSIONER: Yes, yes.

20

MS. CRONK: Exhibit 272, sir, Tab 37.

21

Q. Dr. Kauffman, if we look at the second summary sheet and the information recorded there we see that of the entire group of 10 where you

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had a rating of 2 or greater in terms of probability  
only in the case of Justin Cook did you indicate that  
another medication, I take that to mean other than  
digoxin?

6

A. Yes.

7

Q. All right. May have contributed  
to his terminal events. We see on your coding sheet  
if we turn to page 2 that that is the information  
obviously that you wrote on your coding sheet. Can  
you explain for us, Doctor, what medication or other  
drug was being addressed by you and why you felt it  
may have contributed to his terminal events?

13

A. I think I was thinking in  
terms of the possible role of propranolol when I  
wrote that down.

15

Q. All right. Doctor, in  
indicating to the CDC group that there may have  
been a contribution by propranolol to his terminal  
events, were you suggesting as well that propranolol  
may have played some contributory cause directly in  
the death of the child?

21

A. I was suggesting that as

a possibility, yes.

22

Q. All right. You will recall,  
Doctor, from your prior discussion of the reporting

23

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letters that you did for Mr. Wiley that you  
specifically addressed the issue of propranolol and  
its possible contribution to Justin Cook's death.

3

4

As I understand it, Doctor, you indicated that it  
may well have contributed to the bradycardia and the  
arrhythmias which the child had suffered.

5

6

7

A. That is correct.

8

Q. Was it your view, Doctor,  
when you completed your second reporting letter to  
Mr. Wiley, and bearing in mind what you had indicated  
on your coding sheet for the CDC group, that it  
was that propranolol may have directly contribu-  
ted to this child's death?

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A. As I recall, I still considered  
it a possibility that propranolol may have been a contribu-  
tory cause. I don't remember exactly if I refer  
to that specifically in the second letter.

Q. Doctor, you have indicated in  
your CDC coding sheet as well that you were unable to  
determine whether or not any other medication may have  
modified Justin Cook's response to digoxin. Can you  
help us please as to what you meant by coding that  
particular question in that way?

A. I didn't see any other medica-  
tion record of any other medication being used or





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3 administered to the child which I thought could have  
4 been associated in a drug interaction which might  
5 have resulted in increased digoxin concentrations  
or modified the response to digoxin specifically.

6

7

Q. You did not see any other  
medications?

8

9

A. There was other medication  
but I did not see a medication which I thought would  
specifically modify the response to digoxin.

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Q. Why then, Doctor, ---

A. Well, let me rephrase that.

Q. I'm sorry.

A. I am probably confusing you.

I thought that propranolol could have, and I didn't  
see any other medication that I thought that there  
was a possibility that it would have modified the  
response to digoxin. I was not aware of any known  
drug interaction between digoxin and propranolol, but  
I couldn't be absolutely certain. So, I coded the  
modifier response question as unable to determine,  
simply because of my uncertainty.

You see, I suspect that propranolol  
in and of itself might have contributed to the  
bradycardia but I didn't know if that was an indepen-  
dent response to propranolol, if indeed it did occur,





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or if it was due to an interaction between propranolol  
and digoxin. So, I could say yes, I suspected  
propranolol may have contributed to the terminal  
event but I could not say that this was because of  
a modified response to digoxin.

7

8

9

Doctor, if propranolol had  
had a modifying effect in this child, can you help  
me as to what that would mean; in other words, would  
it render the child less susceptible to digoxin  
toxicity or more susceptible.

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Q. Doctor, if propranolol had

had a modifying effect in this child, can you help  
me as to what that would mean; in other words, would  
it render the child less susceptible to digoxin  
toxicity or more susceptible.

A. Well, a modified response

could be either way.

Q. I see. So, the issue is an

unresolved one in your mind?

A. That is right.

Q. All right. Doctor, could we

turn then if you would please to the case of Kristin  
Inwood. Your completed coding sheet for this child  
appears at Tab 35. Looking at the first page of  
your coded sheet for Kristin Inwood, Doctor, we see,  
in terms of your probability ratings that the child  
appears to have been originally rated at 2, that is,  
slightly more than a least probable categorization.

Do I have that correctly?

A. That is right.





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Q. All right. And then besides that, Doctor, we see in writing a note "Dr. Kauffman called to change this 2 to a 4". Did you, Doctor, after originally rating this child, change your rating from a 2 to a 4?

A. Yes, I did.

Q. Why did you do so?

A. I did that after I was aware of the serum sample with the concentration of 491 nanograms per ml.

Q. I take it then, Doctor, that you then necessarily changed the rating some time after you had completed these coding forms but after as well you had been provided with that information as to the existence of a post mortem serum sample and the level.

A. That is correct.

Q. Right. Doctor, could we turn to your Comments page in your coding section. Really, the last page is an amalgamum of the last two questions on the standard coding form provided by the CDC group. We see there that you indicated that you were unable to make any comment on the likely route, dose or timing of administration. You indicated that it was not applicable. Do you see that, Doctor?





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2 A. Yes, that is correct.

3

4

Q. And if we turn to page 2 of  
your coding sheet.

5

A. Yes.

6

7

Q. You indicated that you were  
unable to determine the cause of digoxin intoxication.  
Can you tell me, Doctor, at the time that you changed  
your probability 2 rating for this child, did you  
also provide the CDC group with any further revisions  
to pages 2 or the Comments page of your completed  
sheet?

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A. Well, no, I did not alter  
those pages. I should have but I did not. I simply  
told them that I thought I should change the overall  
rating and I added that I was taking into considera-  
tion at the bottom of page 1 post mortem blood. On  
page 1, the second question, I indicated to them that  
I was taking into consideration the post mortem blood,  
that I was not originally aware of and they changed  
the code on line number 9 to a 2 rather than a 1.

Q. Doctor, I take it then that  
originally ---

A. But I did not change anything  
else from the original scoring sheet.

Q. Doctor, I take it then at the





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time that you did your original rating you were  
basing it on what you knew of the child's ante mortem  
blood levels, what you knew of the concentrations of  
digoxin found in her fixed tissues and those found  
in her exhumed tissues but not post mortem blood  
sample.

7

8

A. That is correct.

9 Q. What was there, Doctor, that  
10 provided you with sufficient information once you  
11 knew of the post mortem blood sample -- well, I'm  
12 sorry, let me back up. Once you were informed that  
13 a post mortem serum sample did exist and it had a  
14 level of 491 nanograms would that have been sufficient  
15 to permit you to express an opinion as to the likely  
cause of the digoxin intosication?

15

16

A. I might have been able to  
express an opinion with a little more certainty than  
I did originally. I can answer you to that extent.

18

19

Q. Have you fairly, Doctor, to  
be fair to you, have you given that matter any thought?

20

A. No.

21

Q. Are you able to tell us?

22

23

24

25

A. I have not given it any thought  
other than what I indicated in my second letter in  
the police report after I had that information.





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2

Q. To Mr. Wiley?

3

A. Right.

4

Q. Doctor, could you turn as  
well please next to the case of Jesse Belanger.

5

Your coding sheet on this child appears at Tab 24.

6

A. Okay.

7

Q. Do you have that, Doctor?

8

A. Yes.

9

Q. Your probability rating for  
this child, Doctor, was a 3 but we see from  
your summary sheets that your probability rating  
for Stephanie Lombardo was a 4. You have told us  
in evidence over the last day and a half that in  
reaching your conclusions concerning Jesse Belanger  
for the purposes of the reports to Mr. Wiley you  
were relying upon what you observed in the clinical  
course of the child, the terminal events of the child  
and as well the digoxin concentrations in the exhumed  
tissues of the child.

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2 And can you help me, doctor, as to  
3 why when it came time to rate these children to the  
4 CDC group Stephanie Lombardo received a 4 and Jesse  
5 Belanger a 3?

6

A. I suspect that part of the  
7 answer to that question is, as I mentioned earlier,  
8 not every case fit neatly into my preconceived  
9 descriptions, and there were times when I was not --  
10 where I could have ranked them either way in either  
direction.

11

I think that one thing that led me --  
12 well, a general answer is that primarily it was that  
13 I perceived a difference between the medical records  
14 and their clinical course. It is true that their  
15 digoxin data was primarily based on exhumed tissues.  
16 I can't remember if Belanger had -- yes, it was  
17 exhumed tissue, I think they both only had exhumed  
18 tissue concentrations. So the quality of the digoxin  
data was not tremendously different between the two.

19

I think the thing that swayed me  
20 with Lombardo to put her in a higher category was  
21 that she had been fairly stable for approximately five  
22 days after her surgery and then suddenly things  
23 changed. There was a clinical course that meant  
24 something catastrophic had occurred. She over a rather

25





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BB2 2 short period of time developed an irregular heart  
3 rate, bradycardia, a weak pulse, she vomited, she  
4 had all the typical signs of digoxin intoxication,  
5 much more-described in the chart much more typically  
6 than there was for the other child. So that I had a  
7 little more in terms of description for her death  
8 event than I did for the other kids who had similar  
9 digoxin data.

15 So I suppose the succinct answer to  
16 your question would be that the description of her  
17 hospital course and the contrast between her condition  
18 as described during the five days post operatively to  
19 the condition as described during her terminal  
20 events, and the change in her potassium concentration,  
21 led me to rank her with a little higher probability  
than I did with the other baby.

22 Q. Doctor, I note with respect to  
23 Jordan Hines the same probability rating of 5. You





1  
BB3 2 ranked him with a 3 although you ranked Lombard with  
3 a 4. Do your comments hold true for Jordan Hines as  
4 well?

5 A. I think generally that is the  
6 case, yes.

7 Q. Doctor, still on the case of  
8 Jesse Belanger, you will recall that you testified  
9 yesterday and as you confirmed today, that the clinical  
10 course of that child was an ingredient, if you will,  
11 of the ultimate judgment which you reached quite  
12 apart from the digoxin concentrations measured in  
exhumed tissues.

13 However, on my reading of your  
14 completed coding sheet for the CDC group, no mention  
15 is made of the clinical condition of this child, nor  
16 of any significance that you may have attached to it.  
Indeed when we turn to your comments section on  
17 Jesse Belanger your only comment is as follows:

18 "The only basis for postulating  
19 digoxin as the cause of death is  
20 presence of digoxin in exhumed  
21 tissues of an infant who is not  
22 supposed to have received digoxin."

23 Doctor, at the time that you finished  
24 reviewing the medical record of this child was the

25





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2 clinical course considered by you to be significant?

3

4 A. Yes. I thought the clinical  
5 course was not inconsistent with digoxin intoxication,  
6 although in and of itself it certainly wouldn't  
7 prove it. That together with the presence of digoxin  
8 in exhumed tissues in a child who had not been pre-  
9 scribed digoxin, I thought met the criteria that I  
had described for myself to place a child in Category

3.

10

11 I neglected to make any notes about  
12 that, or considerations on the front page of that I  
13 see, and wrote only in that last comment, that is  
14 probably carelessness on my part. I must say that the  
15 comments that I was writing at that time were  
16 informal notes that I had no idea how they were going  
17 to be used, if at all, in the final -- as they were  
18 incorporated into the study. I was simply noting  
19 things as I completed my look at the chart, which were  
20 notes to myself and presumably notes that were going to  
21 be used by the CDC team as they put their report  
22 together.

23

24 Q. Doctor, accepting that fully,  
25 on the basis of the emphasis which you attached to  
his clinical course in our discussions over the last  
day and a half, and indeed in your reporting letters





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BB5 2 to Mr. Wiley, can we agree that on the face of the  
3 two, that is your completed coding report to the CDC  
4 group and your reports to Mr. Wiley, there appears to  
5 be some discrepancy on that issue?

6 A. Looking at them side by side  
7 I would agree with that. I suppose I should say that  
8 the CDC scoring was done a month before I drafted  
9 the so-called police report. I did it in a different  
10 context, at a different time, with a different set  
11 of thoughts and probably a different orientation.

12 When I did the police report a  
13 month later I made more effort, I consciously, I  
14 deliberately did not go back and compare what I had  
15 done on the CDC report because I wanted to do them  
16 independently. I suppose with all the vagaries in  
17 these cases in terms of trying to make estimates and  
18 putting down all the information I am not terribly  
19 surprised that I might have incorporated some  
20 inconsistencies between the two. I don't think it  
21 substantively changes my overall impressions on the  
22 cases.

23 The other thing I think that happened  
24 with the police report was that not having to place  
25 discrete numerical values on decisions I was able to --  
I had the luxury of lumping a little more than I did





1

2 with the CDC evaluation, so I may have made distinctions  
3 in the CDC evaluation that I didn't when I drafted the  
4 police report, I am talking about subtle distinctions.

5 Q. Thank you, doctor.

6 Doctor, I would ask you to turn if  
7 you would to Tab 25, the case of Janice Estrella.

8 A. Just a moment.

9 Q. Do you have that, doctor?

10 A. Yes.

11 Q. Doctor, once again looking at  
12 your coding sheet on Janice Estrella we see the  
13 probability rating of 5, that is most probable,  
14 circled; is that correct?

15 A. That is correct.

16 Q. And beside that, doctor, we  
17 see a handwritten note:

18 "Dr. Kauffman called to change 5 to  
19 2."

20 Do you see that?

21 A. Correct.

22 Q. Did you in fact, doctor,  
23 originally rate this child in terms of probability  
24 of death caused by digoxin as a 5?

25 A. That is correct.

26 Q. And subsequently changed it to  
27 2?





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2 A. That is correct.

3

4

Q. What caused you to alter your  
opinion in the case?

5 A. As I recall the pivotal piece  
6 of information in this child to cause me to give such  
7 a high probability score originally was the serum  
8 concentration of approximately 70. When I was subse-  
9 quently informed that that was gutter blood I could  
10 not completely ignore it, but I had to -- I couldn't  
11 assume that it was any evidence for toxicity either.  
12 So I felt that I had to, because of the ambiguity of  
13 that sample, I had to assign some risk to this  
14 patient but I didn't feel that I could put the risk  
higher than 2. It was a pivotal piece of information  
for me when I was making that decision.

15

16

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18

Q. Doctor, were the comments made  
by you on the likely route, dose and timing of  
administration for this child, at page 4, made before  
or after you changed your probability rating?

19

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A. They were made before and were  
never changed.

Q. They were based then I take it  
in the belief that the post mortem sample was in fact  
a serum sample?

A. That is correct.





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Q. Doctor, I note as well -- I am sorry; in the results then on Janice Estrella, I take it that in the final analysis for the CDC group when you rated the child you placed her as a little better than a very low probability of involvement with digoxin?

A. That is correct.

Q. There are two other children

that you placed in that category, doctor, Brian Gage and Barbara Gionas, both bear a probability rating of 2. I am referring now to the summary sheet of your results, doctor; is that correct, both of those children were assigned a 2?

A. If I can find the right sheet.

Yes, that is correct.

Q. Neither of those children,

doctor, were dealt with in your reports to Mr. Wiley. Indeed you will recall, I suggest, that you indicated that only those cases which afforded sufficient information for comment or analysis were dealt with. Implicitly therefore I suggest that at that time you felt there was insufficient data that allowed you to deal in that way with either Brian Gage or Barbara Gionas; do I have that correctly?

A. That is correct.





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Q. Why then, doctor, and on what information could you then analyze these cases when you were doing your ratings for the CDC group?

5

A. I'm not sure I follow your question.

6

Q. All right, doctor, I'm sorry, perhaps again it was put awkwardly. They were not dealt with in the police report.

9

A. Right.

10

Q. And you said in the police report that the cases not dealt with were ones where there was insufficient information available to you to permit an assessment.

13

A. Right.

14

Q. In the case of the CDC ratings however, neither of these children were put in the least probable category.

17

A. Right.

18

Q. They were nudged over that, if you will. What information was available to you that led you to be in a position to deal with Brian Gage and Barbara Gionas and to assign a probability rating of 2 for these cases?

22

A. Okay. Again I think these two children fell into the category of children that

23

24

25





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2 didn't neatly fit either of my categories. I can  
3 tell you the specific criteria if I can find my  
4 notes that swayed me to put them in a 2 rather than a  
5 1, if you will give me just a moment to pull the notes  
6 on them. I should say while I am doing the search  
7 I really viewed the rankings of 1 and 2 as being  
8 children with which there was very little confidence  
9 that digoxin was indeed related to their death.

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2 And as I said earlier I am not sure that I really  
3 could make a real distinction between the children  
4 who received rankings of 1 or 2. It may be an  
5 artifactual distinction, but I did try to at least  
6 attempt to do it, and I would caution people not to  
7 assign a great deal of quantitative value to the  
8 difference between the 1 and 2.

9 Q. Well, Doctor, may I stop  
10 you there for a moment then?

11 In either the case of Brian Gage or  
12 Barbara Gionas bearing in mind what you have just  
13 said, was there in your view any real basis for a  
14 belief or judgment that digoxin intoxication had  
15 caused the death of either child?

16 A. There was some clinical  
17 evidence. For example - that I couldn't ignore -  
18 for example let me summarize Gage for you. This  
19 child was a severely cyanotic child who had a  
20 transposition with an intact septum so the blood  
21 between the lungs and the body could not mix and  
22 he was very cyanotic.

23 He had a balloon septostomy at 9  
24 days. He remained cyanotic but he was fairly stable  
25 as nearly as I can tell from the chart but he was  
still persistently cyanotic so he had been scheduled





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2 for future surgery.

3 At 0320 on the day of the scheduled  
4 surgery he suddenly developed vomiting, bradycardia,  
5 typical signs again of digoxin intoxication and I  
6 really couldn't ignore the description of those  
7 symptoms when I looked at it carefully and put him  
8 in a 1 although that was really - really his ante  
9 mortem serum concentration which I had wasn't  
10 inconsistent with his prescribed dose. So those met  
11 the criteria that I had set out for myself and  
12 technically they met the criteria that I had set out  
13 for 2 so I felt I had to put him in 2.

14 Now if we look at Gionas, this was a  
15 little different, but again it was an ambiguous case  
16 in terms of my self-imposed criteria.

17 This child came in the Hospital at one  
18 day of age with a coarctation and a hypoplastic  
19 aorta which means that he or she, I am not sure what  
20 the gender was.

21 THE COMMISSIONER: She.

22 MS. CRONK: Q. Barbara.

23 A. Barbara, okay. Which meant  
24 that her heart was unable to provide enough blood  
25 flow to her body, and a lot of the blood was being  
shunted to the lungs so she came in in severe





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3 2 congestive heart failure.

3

4 She was operated on twice and  
remained in failure and went progressively downhill.

5

6 leading up to her death and her death event did not  
7 particular impress me as being typical of digoxin  
8 intoxication, but she technically met my self-imposed  
9 criteria for Category 2 because she had ante mortem  
10 serum concentrations consistent with her prescribed  
11 dose as the other baby, but she had ambiguous post  
mortem digoxin data.

12

13 And those were two of the three criteria  
I had set out so I felt I had to put her in a 2.

14

15 Again I say I think that either of  
16 these children could have - you could argue that they  
17 should be in one or the other and that is why after I  
18 did this and then sat back and looked at it I really  
19 wasn't sure whether there was any real difference in  
the probability between the ones I had given a 2 to  
and the ones I had given a 1 to.

20

Q. Thank you, Doctor.

21

22 Doctor, dealing with the category of  
children where you did assign a probability rating of  
1, as you know ---

23

THE COMMISSIONER: Before you leave

24

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2 the Category 2, these are both based, are they not,  
3 upon digoxin levels which were read ante mortem?

4 THE WITNESS: I think that is included  
5 they both had ante mortem levels.

6 THE COMMISSIONER: Well other than  
7 the fact that their deaths were presumably consistent  
8 with digoxin intoxication, what you are assuming is  
9 that somehow it was the therapeutic dosage, intended  
therapeutic dosage that killed the two of them?

10 THE WITNESS: No, no, not at all.

11 THE COMMISSIONER: Then what is the  
12 significance of the ante mortem readings?

13 THE WITNESS: The significance was  
14 that if the ante mortem serum concentration was  
15 consistent with their therapeutic dose as prescribed --

16 THE COMMISSIONER: Yes.

17 THE WITNESS: - they could have fallen  
18 into either rating 1 or 2, based solely on that  
criteria.

19 THE COMMISSIONER: Yes, but you would  
20 have presumably if there hadn't been those readings,  
21 those high readings you would have put these two  
children in 1, would you not?

22 THE WITNESS: High readings, on the  
23 tissue?

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THE COMMISSIONER: No, no. I am talking of the ante mortem readings. Weren't they ---

THE WITNESS: I don't think they had elevated ante mortem ---

MS. CRONK: In fact, sir, to clarify that so that the record is clear only one of those two children had an elevated level. Brian Gage had 3.5 and Barbara Gionas' last ante mortem was a 1.9 as I recall it.

THE COMMISSIONER: But I still don't quite understand... Let's just look at Gionas then.

MS. CRONK: That is Tab 32, sir.

THE COMMISSIONER: Yes, I have that.

I thought I had a note here that as far as Gionas was concerned she had met your criteria because there were ante mortem readings, but I have got that wrong?

THE WITNESS: I believe there are ante mortem levels on both of them.

THE COMMISSIONER: Yes, but if the ante mortem level is within the therapeutic range how does that affect you at all?

THE WITNESS: If it is?

THE COMMISSIONER: Yes and Gionas





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2 apparently was.

3 THE WITNESS: Both of them - I accepted  
4 both of them as being within the therapeutic range.  
5 One being on the high side but I interpreted the 3½  
6 as being within an acceptable or non-toxic range also.

7 THE COMMISSIONER: Well, leaving aside  
8 for the moment that sometimes it is a fine line between  
9 1 and 2 and is one that you had difficulty drawing but  
10 I still don't quite understand why either of these  
children went into the 2.

11 THE WITNESS: Well, with respect to  
12 Gage I suspect it was primarily due to the description  
13 of the terminal event.

14 THE COMMISSIONER: All right. Is  
15 there that much distinction between his terminal events  
16 and those of many of the others? A great many of them  
had sudden bradycardia ---

17 THE WITNESS: I think at the time I  
18 was doing this it apparently impressed me that it was.  
19 Maybe if I went back and looked at them side by side  
20 I wouldn't feel the same today but I think that is  
21 why I did what I did on that particular day.

22 THE COMMISSIONER: All right. You  
23 think you put Gage in 2 because of the nature of the  
24 terminal events; is that right?

25





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2 THE WITNESS: Along with the normal,  
3 what I thought was normal pre mortem serum concentration.

4 THE COMMISSIONER: Well I don't really  
5 see what the pre mortem serum concentration has to do  
6 with it at all if it is within the therapeutic range.

7 THE WITNESS: Only to the extent that  
8 if the child had this kind of clinical course and had  
9 an elevated ante mortem level it would go in a higher  
category.

10 THE COMMISSIONER: Yes. All right.  
11 I don't want to press it too much. I just don't see  
12 the difference between Gage and Gionas on the one  
13 hand and all the others that you had in number 1 and  
14 almost all of them we have heard time and time again  
15 that the terminal events were consistent with their  
16 clinical condition and were equally consistent with  
digoxin poisoning.

17 THE WITNESS: I think that there are  
18 degrees of ---

19 THE COMMISSIONER: Of likelihood?

20 THE WITNESS: Of likelihood in the  
21 description. In other words to me the description of  
22 the terminal event of Gage is quite different from  
that of Gionas.

23 THE COMMISSIONER: Yes, and you find

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2 it more consistent with digoxin?

3 THE WITNESS: I find Gage's terminal  
4 event description more consistent than Gionas'  
5 terminal event.

6 THE COMMISSIONER: All right, that  
7 might account for Gage being in 2, but it certainly  
8 doesn't account for Gionas.

9 THE WITNESS: I was using two different  
10 of two of the three different criteria to put Gionas  
11 in.

12 THE COMMISSIONER: All right. Why  
13 did you put them - if you put Gage in 2 because of  
14 that nature of the terminal events why did you put  
15 Gionas in?

16 THE WITNESS: The two of the three  
17 that I was applying Gionas to was according to my  
18 notes ante mortem serum concentration consistent with  
19 prescribed doses which wouldn't allow her to be any  
20 higher than a 2 at the most.

21 THE COMMISSIONER: You would probably  
22 put her in a 1 if there were nothing else?

23 THE WITNESS: Post mortem digoxin  
24 data from exhumed tissue in her case which I  
25 couldn't ignore but they were ambiguous. They were  
ambiguous because they were exhumed tissue but I





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9 2 couldn't ignore them.

3 THE COMMISSIONER: If I understand  
4 it really the ante mortem doesn't mean anything.  
5 The post mortem, it is ambiguous and it may conceivably  
6 support digoxin intoxication so it would really be  
7 because of the post mortem tissue readings.

8 MS. CRONK: Sir, I don't mean to  
9 interrupt; there may be a misconception here.

10 You will recall that the Doctor's  
11 evidence has been that he composed and designed  
12 written criteria.

13 THE COMMISSIONER: That is right.

14 MS. CRONK: The criteria that he is  
15 referring to are direct quotes, as I understand it,  
16 Doctor, from the written criteria that he applied  
17 for a rating of 2.

18 THE COMMISSIONER: Yes.

19 MS. CRONK: Such that if Gionas  
20 met two of three criteria ---

21 THE COMMISSIONER: Yes. One of those  
22 three then?

23 MS. CRONK: If you turn to Tab 1,  
24 sir, you will find Dr. Kauffman's - please stop me  
25 if I am incorrect, Doctor - you will find Dr.  
Kauffman's letter to Dr. Smith and at page 3 under





1

10 2 your rating 2 you will see three criteria set out.

3

4 patient, Dr. Kauffman has told us, had to meet at  
5 least two of the three.

6

7 Q. Dr. Kauffman, are you now  
8 telling us that Barbara Gionas technically met two of  
9 the three?

10

A. Yes. Can I expand on that?

11

Q. Please do.

12

A. Rating 2 they had to meet  
13 two of those three criteria.

14

15

16

Now in the case of Gionas criterion  
No. 1 is clinical condition of course not inconsistent  
with digoxin toxicity. I thought that applied to Gage  
but not to Gionas. "Ante mortem serum concentration  
consistent with therapeutic digoxin dose" - I thought  
that did apply to Gionas.

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THE COMMISSIONER: If it is

consistent with a therapeutic digoxin dose I don't see why one should be suspicious at all. That would seem to be what should happen.

THE WITNESS: These were characteristics

which I inserted there that would not allow it to be a 3.

THE COMMISSIONER: That is right.

That brings it down from a 3 to a 2, but how does it get ---

THE WITNESS: Well, if the patient

had some characteristics of 3.

THE COMMISSIONER: I see.

THE WITNESS: Now Gionas really

couldn't fit into the rating, any of the 1 rating criteria. There was a record of receiving digoxin.

She was receiving appropriate dose and

her serum and tissue concentrations weren't - well, her serum was consistent but she had ambiguous tissue concentrations in my judgment at that point and she didn't fit criterion 3 of rating 1.

So I really couldn't legitimately put her in that category and she did technically meet two of the criteria of Category 2 and she certainly didn't fit Category 3, so that is where she fell.





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THE COMMISSIONER: Well now Gionas

I take it under rating 2 - Gionas doesn't fit any of the - well, I guess there is presence in exhumed or fixed tissues - no, but digoxin was prescribed for her.

THE WITNESS: Yes.

THE COMMISSIONER: She couldn't possibly be in rating 3 because all she satisfies is the second criteria.

THE WITNESS: That is correct.

THE COMMISSIONER: She couldn't be in rating 3. Now when you come to rating 2, the second one of those seems to be one that would apply only if she were in danger of being put in rating 3.

THE WITNESS: I think I agree with you.

THE COMMISSIONER: So I wouldn't have thought that would apply to her at all. I would have thought that with Gionas that unless she - I suppose if she satisfied condition 1 and condition 3 ---

THE WITNESS: But in my judgment she did not satisfy condition 1.

THE COMMISSIONER: All right. Then I don't think she should have been in rating 2 because the second one doesn't really move her up from 1. It





13

1 only takes her down from 3 which she shouldn't have  
2 been in in the first place.

4 THE WITNESS: No, it is the third  
5 criterion that keeps her from being a 1. And the  
6 fact that she really doesn't fit any other criterion  
7 in rating 1.

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THE COMMISSIONER: Well, I'm not satisfied yet, but carry on.

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THE WITNESS: I will try to respond better if I can. I share your concern because, as I said, when I went to fit these kids into these rating cubbyholes I had trouble fitting some of them.

7

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THE COMMISSIONER: Well, let's just look at Gionas just for a moment to see. First of all, you say that:

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"Her clinical condition and course was not inconsistent with digoxin intoxication, yes or no".

THE WITNESS: I didn't think it was typical of digoxin toxicity.

THE COMMISSIONER: Well then, she wouldn't have made the first one?

THE WITNESS: I didn't think she made the first cut, no.

THE COMMISSIONER: No. And the second one:

"The ante mortem serum concentration was consistent with a therapeutic digoxin dose which was prescribed."

That was correct, she did make that?

THE WITNESS: That's correct.





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THE COMMISSIONER: But that won't move her from 1 to 2?

THE WITNESS: But it keeps her from being a 3.

THE COMMISSIONER: It keeps her from being a 3, that's right.

THE WITNESS: Among other things.

THE COMMISSIONER: And she may have had ambiguous post mortem digoxin concentrations not inconsistent with therapeutic doses but also not inconsistent with digoxin toxicity.

THE WITNESS: All right.

THE COMMISSIONER: So, she did have No. 3, Rating 2.

THE WITNESS: Right.

THE COMMISSIONER: She also had No. 2 but that doesn't really tell us anything because the other 36 children, other 28, or whatever they were, presumably had all the same, they had ante mortem serum concentrations inconsistent with therapeutic digoxin?

THE WITNESS: Well, some of them didn't have any concentration data. Some of them had never received digoxin and had not had any data produced on them. So, the ones that ended up being









DD.3

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2 l's were a composite of the three criteria under  
3 Rating 1.

4 MS. CRONK: May I be of some assistance,  
5 sir, if possible?

6 THE COMMISSIONER: You can try.

7 MS. CRONK: I'll try.

(2)

8 Q. Doctor, I would ask you to take  
9 a look at Criteria 2 under Rating 1.

10 A. Yes.

11 Q. Look at that criteria. It says:

12 "The patient to satisfy that  
13 criteria had to have been receiving  
14 appropriate digoxin dose."

15 Let's stop there. Was Gionas  
16 receiving appropriate digoxin doses?

17 A. I thought she was, yes.

18 Q. "And her serum and tissue  
19 concentrations were not inconsistent  
20 with the dose."

21 Let's leave out the tissue for a  
22 moment because you have said that is ambiguous, but  
23 the serum concentration ante mortem was consistent  
24 with the dose that she was receiving, do I have that  
25 right?

26 A. I thought it was, yes.





DD.4

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Q. Yes. So, from that approach she satisfied at least one of the conditions under Rating 1 which would have placed her in that group, is that right?

A. That is right.

Q. And then if we look at Rating No. 2 there is a criteria that is quite similar but more restrictive because this time you are speaking only about serum levels and more particularly ante mortem serum levels and that is No. 2 that we have just looked at, and she satisfied that as well?

A. That is correct.

Q. So, at that point she could make it into Rating No. 1 and she is half way into making it into Rating No. 2, all right?

THE COMMISSIONER: I am sorry, because of what, No. 2?

MS. CRONK: Yes, sir.

THE COMMISSIONER: And Rating 2?

MS. CRONK: Yes, sir. In each case ---

THE COMMISSIONER: Can you tell me, what's the difference between ---

MS. CRONK: If you take a look, sir, at the criteria under Rating No. 1, Barbara Gionas.

THE COMMISSIONER: Yes.





DD.5

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MS. CRONK: She was receiving, in Dr. Kauffman's view, an appropriate digoxin dose and her serum was not inconsistent, the concentration of the serum was not inconsistent with the dose.

6

THE COMMISSIONER: That's right.

7

MS. CRONK: Now, the difficulty is that the tissue concentrations he feels were ambiguous. They could or they may not have been consistent with the therapeutic dose.

10

THE COMMISSIONER: Yes.

11

MS. CRONK: Right.

12

Moving then to Rating 2 to see if she satisfied it.

14

Q. Dr. Kauffman, her ante mortem serum concentration you felt was consistent with the dose that she was prescribed, correct?

16

A. Yes.

17

Q. All right. So, she satisfied that criteria. So, she is half way into being in Rating Group No. 2, she satisfied one criteria.

20

THE COMMISSIONER: You have lost me when you do that.

21

MS. CRONK: I'm sorry.

22

THE COMMISSIONER: Because I don't see anything in Rating 2, No. 2 which moves her from

24

25





DD. 6

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2 Rating 1 at all.

3

4 MS. CRONK: I am suggesting you are  
5 entirely right, sir, that at that stage she could  
6 almost be in either 1 or 2 by virtue of the way  
7 Dr. Kauffman has defined his criteria.

8

THE COMMISSIONER: Yes.

9

MS. CRONK: All right.

10

11 THE COMMISSIONER: Well, it seems to  
12 me that Rating 2 and No. 2 and Rating 1 and No. 2 are  
13 practically the same thing.

14

THE WITNESS: I agree.

15

16 MS. CRONK: I think he said that too,  
17 sir.

18

19 THE WITNESS: I agree with you.

20

21 THE COMMISSIONER: All right, okay.

22

23 MS. CRONK: Q. And then do we not add  
24 one more ingredient into the picture, Dr. Kauffman,  
25 and, that is, that this child satisfied another  
criteria as you had defined them in your Rating Group 2  
and, that was, you didn't know what to make of the  
concentrations in her tissues?

26

A. That is correct.

27

28 Q. So, you could no longer say that  
29 she fits solely into one because it is possible those  
30 tissue concentrations could have been indicative of  
31 toxicity?

32





DD.7

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2 A. It could be either way. In  
3 my judgment at that time maybe I should have inserted  
4 a 1-1/2 or something but I didn't.

5 Q. I'm not sure, sir, I can take  
6 it much beyond that.

7 THE COMMISSIONER: Yes.

8 MS. CRONK: I may have even muddied  
9 the waters even further.

10 THE WITNESS: I think this illustrates  
11 the ambiguity if you will between the Ratings 1 and 2.  
12 We may be splitting hairs.

13 THE COMMISSIONER: Well, I think we  
14 probably are splitting hairs. If we split 2 into 1 -  
15 two hairs in one direction ---

16 THE WITNESS: Profused hairs.

17 THE COMMISSIONER: And 26 of them into  
18 another. I just don't quite get the distinction.  
19 However, we'll see. Perhaps it will dawn on me before  
20 the end of the week.

21 MS. CRONK: Q. Dr. Kauffman, there is  
22 one other area that I would like to cover with you  
23 and it has to do with those 26 children that you did  
24 rate with the probability rating of 1.

25 As you will recall, sir, an expurgated  
copy of the CDC group report was filed here as an





DD.8

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2 exhibit yesterday. I don't think you need to refer  
3 to it but if you wish to please indicate so. But I  
4 can tell you that at page 13 of that report it is  
5 suggested that according to your ratings patients  
6 could have received a rating No. 1 for one of two  
7 reasons; the first reason was that limited data were  
8 available on the particular patient. The second  
9 reason was that data was available but suggested a  
10 low probability that death was due to digoxin  
11 intoxication. Is that a correct statement, Doctor,  
12 in your view of the basis upon which you placed  
13 patients into Rating Group No. 1 for one of those two  
14 reasons?

15

16 THE COMMISSIONER: Where is this, on  
17 page 13 you say?

18

MS. CRONK: Yes, page 13, sir.

19

THE COMMISSIONER: Where?

20

MS. CRONK: The second full paragraph  
21 of the last sentence. Would it help you, Doctor, to  
22 have it in front of you?

23

THE WITNESS: I think I should look at  
24 it because I think there may be the potential of a  
25 subtle meaning here which may not fit the way I was  
actually using my own criteria at the time, I'm not  
sure.





DD. 9

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2

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MS. CRONK: Q. Look at page 13, Doctor,  
if you would, please. Do you have it?

4

A. I have page 13.

5

6

Q. Second full paragraph beginning  
with the words "A discussion". Do you see that, Doctor?

7

A. No.

8

Q. The second full paragraph starts  
with the words "A discussion".

9

A. Not on my page 13. Do I have  
the wrong page?

11

Q. May I see? "A discussion"  
right there, the second full paragraph.

13

A. Oh, okay.

14

Q. I'm referring to the last  
sentence in that paragraph.

15

A. Okay.

16

Q. It says:

17

"Patients may have received ... "

18

A. Okay, now I see it.

19

Q. "... a low rating to Question  
Number 1 for one of two reasons:

21

limited data were available ... "

22

that's the first reason:

23

" ... or available data suggested a  
low probability that death was due to  
digoxin intoxication."

24

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DD.10

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My question to you, Doctor, is that an accurate statement of the basis upon which you placed children in Rating Group No. 1, for one of those two reasons?

A. Well, it's subtlety of whether to say that I agree with the limited data, I think, because two of my criteria for Rating 1 said that no digoxin measurements were done. So, that would be limited data, could fall within that definition. The second one bothers me a little bit, I'm not sure it reflects the total or the true meaning or not and I need to think about it for a moment.

Q. Okay.

A. If you are thinking of it in terms of data suggesting a low probability, in other words, there is positive data that demonstrates a low probability, that's a little bit different than saying that there were no data to demonstrate toxicity.

Q. All right. Well, Doctor, I don't wish to cause any of us more trouble with the language than necessary. Can we try it this way.

A. Frankly, at the time I was using this I wasn't thinking of those kinds of subtleties. I thought I knew what I meant and I was doing it that way.





DD.11

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Q. Doctor, were there, amongst

the 26 cases that you rated with a 1 cases where there was data available which you felt in a positive way established that there was very little if any chance that those children could have died from digoxin intoxication?

A. Well, the majority of those

26 patients were fit into Criterion No. 2 which they were receiving an appropriate dose according to the chart and their serum concentrations were not inconsistent with the dose they were receiving.

Q. All right. Doctor, I take it, leaving those children aside and ones that fit into that group, there were some where you just couldn't tell because there was insufficient data available.

A. There were two who had no

record of receiving digoxin and in whom no digoxin measurements had been made; there were five who were receiving an appropriate dose and no digoxin measurements were made.

Q. All right. Well, Doctor, are the ones that fell into the first group that you are describing those in which you would be prepared to say as a pharmacologist that there was a very remote possibility if any that digoxin intoxication





DD.12

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2 contributed to their deaths?

3

A. Yes.

4

5

Q. May I have the identity of  
those please, Doctor?

6

A. I have a list here if you want.

7

Q. All right.

8

A. I can give you a handwritten  
list, I have nothing else, from my notes.

9

10

Q. Thank you. Which category is  
that?

11

12

13

A. This category here. These are  
the ones who were receiving digoxin and had levels  
which were consistent with the dose they were receiving.

14

15

Q. All right. Doctor, you have  
shown me that there are 20 children of the 26 that  
you would place in that category.

16

17

MR..STRATHY: I'm sorry, that  
category is very remote?

18

MS. CRONK: Little if any possibility.

19

20

21

THE WITNESS: Are you making a  
distinction between those and the others in Category 1  
or Rating 1?

22

23

24

25

MS. CRONK: Q. I was attempting to,  
Doctor. Perhaps we had better do this again. What I  
am effectively asking you, Doctor, is, looking at your





DD.13

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2 group of 26 are there, amongst those cases, cases  
3 where you as a pharmacologist feel that there is only  
4 a very remote if any chance at all that death was  
5 due to digoxin intoxication? Are there any that you  
6 would thus describe?

7

A. Well, I thought when I was  
7 ranking these that that was the definition of  
8 Category 1, Rating 1. I think I am starting to  
9 understand what you're asking, I'm not sure.

10

Q. Well, let me try again.

11

A. These 20 - is it 19 or 20, I  
12 didn't count them?

13

Q. 20.

14

A. 20 who met, who were receiving  
14 an appropriate dose according to the record and who  
15 had a documented concentration which I thought was  
16 appropriate to that dose. There is positive data  
17 which would mitigate against toxicity. Those who had  
18 no record of receiving digoxin and in whom no digoxin  
19 measurements were done have no ----

20

THE COMMISSIONER: I'm sorry, I'm  
21 not too sure what you mean by "were done", were found?

22

THE WITNESS: Pardon?

23

THE COMMISSIONER: Did they attempt -  
23 you see, I can understand if they had no record of  
24

25





DD.14

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2 receiving digoxin and if they were exhumed or something  
3 and there were no digoxin traces of anything found, I  
4 can understand that child you can pretty well dismiss  
5 as having died of a digoxin overdose. I don't know if  
6 we can, but certainly it would help if there was some  
7 positive evidence on which you can base it. But what  
8 happens if they don't take any measurements at all,  
9 you don't know.

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THE WITNESS: That's what I was trying to say. I think I'm starting to understand your question.

MS. CRONK: That was the point I was awkwardly trying to make, sir.

THE WITNESS: Those who met Criterion 1 and Criterion 3, based on pharmacologic data, you don't know.

MS. CRONK: Q. And how many fall into those two groups? You don't have the list any more.

A. I don't have the list any more. I think it is 6.

Q. And 20 fall into the other?

A. Right. I can tell you why I put that in Rating 1 and, that is, because I was asked to look at or rate these cases primarily on pharmacologic data and secondarily on clinical data. There





DD.15

1

2 was somebody else looking at exclusively clinical,  
3 making ratings based on primarily clinical data.

4 So, when I didn't have pharmacologic  
5 information I gave him a low probability. That was a  
6 decision on my part at the time.

7 Q. Well, Doctor, looking at your  
8 handwritten list, amongst our group of 36 there are  
9 then 6 children where the information simply wasn't  
available to you or you couldn't tell?

10 A. There were no measurements,  
11 that's right, pre mortem or ante mortem - I mean, post  
12 mortem.

13 Q. Those were, would you kindly  
14 confirm that for me, please, Dion Shrum, David Taylor,  
15 and Tony Velasquez, Antonio Adamo, D'Arcy MacDonald  
and the Perreault baby, amongst our group of 36?

16 A. That is correct.

17

18

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E/DM/ak

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Q. Am I correct, Doctor, that in

the other 20 cases there was positive data available to you which would lead you, as a pharmacologist, to say that there was a very remote chance, if any, that digoxin intoxication caused the death of those children?

8

A. That is correct, and there was

no data to the contrary.

9

10

Q. Thank you, Doctor, I think maybe we are there.

11

12

13

14

15

THE COMMISSIONER: Which children

were they with no record of receiving digoxin I know digoxin may have been done, but I would have thought that they were the first ones that should be - which ones are they?

16

17

THE WITNESS: They are criterion 1 and 3, the middle and the right hand column of my original list.

18

19

THE COMMISSIONER: Why are they separated here then?

20

21

22

23

24

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THE WITNESS: Because in meeting

criterion 1 they had no record of ever receiving digoxin; those in criterion 3 were receiving digoxin therapeutically but no measurements were done. The only thing that differentiated those two groups were





EE2

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that one had digoxin prescribed, the other one did  
not.

4

5

THE COMMISSIONER: The two are  
Perreault and ---

6

THE WITNESS: I don't have the list.

7

THE COMMISSIONER: Would you look  
at the list.

8

9

MS. CRONK: I think that child,  
Mr. Commissioner, was not in our group of 36.

10

11

THE WITNESS: That was the child that  
I reviewed for the CDC, he was not a subject of this ---

12

13

THE COMMISSIONER: We don't have  
to worry about him.

14

THE WITNESS: No.

15

16

THE COMMISSIONER: The only other  
one is Perreault and he is the one who apparently  
never received ---

17

18

THE WITNESS: He was receiving  
digoxin therapeutically but no measurements were  
made.

20

21

THE COMMISSIONER: And Shrum, Taylor,  
Velasquez and MacDonald and Adamo ---

22

23

THE WITNESS: Were not receiving  
digoxin and no measurements were made.

24

25

THE COMMISSIONER: And you can't help





EE3

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2 : me, tell me as to why?  
3

4 THE WITNESS: No.

5 THE COMMISSIONER: Somebody will I  
6 hope some time.

7 MS. CRONK: There is one other point  
8 that flows from that, Mr. Commissioner.

9 THE COMMISSIONER: Yes.

10 MS. CRONK: Q. When you say that  
11 they were not receiving digoxin, Doctor, are you  
12 talking about that at a specific point in time,  
13 because the evidence before us suggests that the  
14 children had received digoxin during their lives?

15 A. According to my notes there was  
16 no record on the Hospital record that they had  
17 received digoxin.

18 Q. At the Hospital for Sick  
19 Children?

20 A. At the Hospital, yes.

21 Q. Thank you, Doctor. Doctor,  
22 one final question and then I am going to sit down  
23 before I get myself into trouble.

24 THE COMMISSIONER: You are going to  
25 tell me though, Miss Cronk, that this list of Shrum,  
Taylor, Velasquez, Adamo and MacDonald all had been  
receiving digoxin and that is why they were not





Kauffman, dr.ex.  
(Cronk)

EE4

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exhumed I take it.

3

MS. CRONK: Well, sir, maybe you have connected the two together there too quickly.

4

THE COMMISSIONER: Yes, all right.

5

MS. CRONK: My understanding of what the doctor has just said is that there was no record that those children had received it at the Hospital for Sick Children, I will have to verify that from my own records.

6

THE COMMISSIONER: Were tests done on any of these five children, Shrum, Taylor, Adamo, Velasquez and MacDonald?

7

THE WITNESS: I had no record of digoxin measurements when I did the ratings.

8

THE COMMISSIONER: And I take it not in Mr. Cimbura's report, right.

9

MS. CRONK: Mr. Commissioner, may I suggest, I had hoped to finish before the break, we are now 10 minutes over the time for our break and perhaps I can clarify this matter when we return, sir.

10

THE COMMISSIONER: All right. I tell you what I want to know, I just want to know - I can understand that you are basing any level above 1 which have to have some toxicology to make that possible, some indication of something, if you don't

11

12





Kauffman, dr.ex.  
(Cronk)

EE5

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2 have any indication you don't put it in one. But  
3 that wouldn't satisfy me, because if in fact the  
4 children died under circumstances that could have  
5 been digoxin toxicity, or could not have been, the  
6 fact that we don't have any information doesn't mean  
7 anything at all to me. Because if we don't have  
8 any evidence one way or the other toxicology doesn't  
9 mean anything to me at all.

10 THE WITNESS: That is correct.  
11 Dr. Nadas who was doing the cardiology review of  
12 these cases may very well have rated them 5, 3,  
13 or 4 when I ranked them a 1, because I was looking  
14 at the digoxin data and he was looking at the cardiology  
15 data. I looked at the clinical data secondarily,  
16 but I had to have something about digoxin there  
17 before I went beyond that.

18 THE COMMISSIONER: Up to even  
19 moving it up to a 1.

20 THE WITNESS: Because I was asked to  
21 look at it from that perspective and I think it is  
22 highly likely, although I haven't looked at the  
23 comparison, that his ratings of some of these cases  
24 were probably quite different from mine because he  
25 really wasn't considering the digoxin data primarily,  
he was looking at the cardiac picture of these





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Kauffman, dr.ex.  
(Cronk)

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2

EE6 children, the other side of the coin.

3

4

Now the report, I suspect attempted  
to incorporate these and put them together but that  
wasn't my job at the time.

5

6

THE COMMISSIONER: Yes, all right,  
thank you. We will take 15 minutes.

7

8

MS. CRONK: Thank you, sir.

---Short recess.

9

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EE2.2 2 A. I included any transfer notes,  
3 or notes regarding a dose prior to arriving, or in  
4 The Hospital for Sick Children's records as well as  
5 a record of any that might have been received during  
6 their hospitalization.

7 Q. Thank you, doctor.

8 A. In other words, the patient's  
9 history as well as the Hospital course.

10 Q. To which children, doctor, which  
11 of your 26 children, doctor, satisfied that criterion?

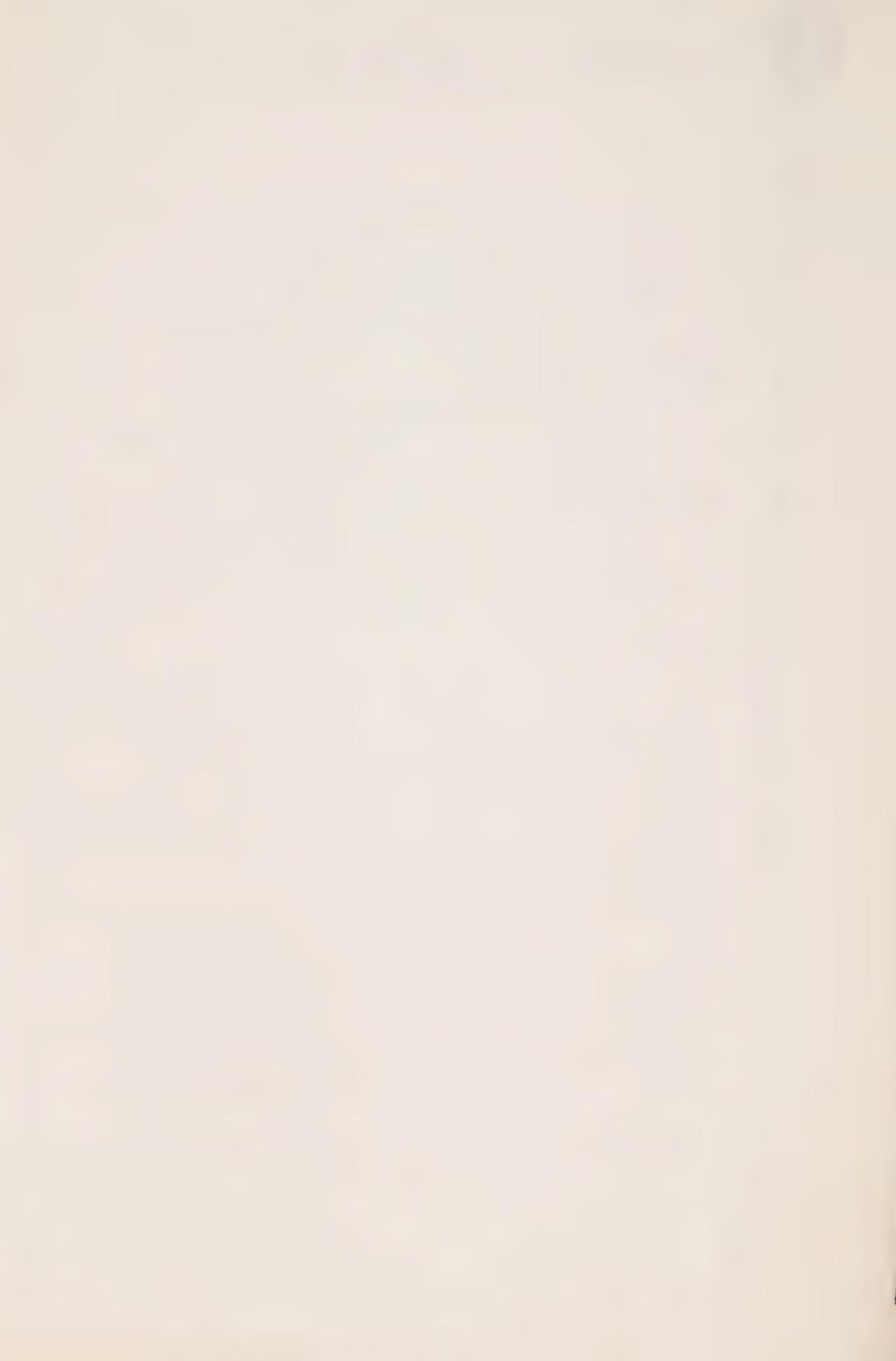
12 A. That is No. 1, I have Perreault  
13 listed.

14 Q. And, doctor, your second  
15 criterion under Rating No. 1 is, the patients were  
16 receiving appropriate digoxin dose and serum and  
17 tissue concentrations were not inconsistent with that  
18 dose, meaning I take it they were consistent with the  
19 doses that they were prescribed?

20 THE COMMISSIONER: No, should we put  
21 in "and any serum and tissue concentrations", does  
22 that mean that there were in every case serum and  
23 tissue concentrations and that they were not instances

24 THE WITNESS: It should have been  
25 serum and/or.

26 THE COMMISSIONER: Well if there may





Kauffman  
dr.ex. (Cronk)

1  
EE2.3 2 have been neither, there may have been neither serum  
3 nor tissue concentrations.

4 THE WITNESS: That is No. 3.

5 THE COMMISSIONER: Yes, all right,  
6 serum and/or tissue concentrations, there were at  
7 least serum or tissue concentrations and those that  
there were --

8 THE WITNESS: Yes.

9 THE COMMISSIONER: Okay.

10 MS. CRONK: Q. Let me just follow  
11 up on that, those that were were consistent with the  
12 appropriate digoxin dose that had been received.

13 THE COMMISSIONER: And there were  
14 some.

15 MS. CRONK: Q. And there were some?

16 A. Yes.

17 Q. Which children, doctor, by  
18 name, satisfy that criterion, if you would please?

19 A. That included Warner --

20 THE COMMISSIONER: They are the  
21 ones --

22 THE WITNESS: They are the long list.

23 THE COMMISSIONER: That is the long  
24 list?

25 THE WITNESS: Of the 20, yes.





Kauffman  
dr.ex. (Cronk)

EE2.4

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THE COMMISSIONER: All right, thank  
you. This list is going to be prepared, typed out.

3

4 THE WITNESS: Okay.

5

6

MS. CRONK: Q. Doctor, may we turn  
to the third criterion; the patients were receiving  
appropriate digoxin dose, no digoxin measurement done,  
which children fulfilled that criterion?

7

8

A. That was Shrum, Taylor, Velasquez,  
Adamo, MacDonald.

9

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Q. And, doctor, that is where I  
think I misled you. I take it then those children  
were receiving digoxin but you felt it to be an  
appropriate dose and there were no measurements  
available for you?

A. Correct.

THE COMMISSIONER: The only one we  
are concerned with is Perreault. I don't quite  
understand, there was no record of he ever having  
received digoxin, but for some reason they never  
examined to find out whether he had any digoxin in  
his tissue, is that right?

THE WITNESS: To my knowledge, I  
apparently didn't have any data on him when I did the  
review.

THE COMMISSIONER: I wonder if before





Kauffman  
dr.ex. (Cronk)

1

EE2.5 2 tomorrow somebody can find out why that was not done.  
3 Because I can well understand not exhuming if it  
4 isn't going to tell us anything, but if Perreault  
5 didn't have any at any time and he did turn out to  
6 have digoxin in his tissue that would put him  
7 exactly in the same category as the other four.

8 MS. CRONK: Well, Mr. Commissioner,  
9 before that thought progresses further. It is my  
10 understanding and the evidence before you today is  
11 that no digoxin was given, although originally ordered,  
12 to that child while he was at The Hospital for Sick  
13 Children, but that he in fact did receive some prior  
14 to entering the Hospital; that is the evidence before  
15 you to date, sir.

16 Q. My question to you, Dr.  
17 Kauffman, I take it you were unaware that the child  
18 had received some prior to entering The Hospital for  
19 Sick Children?

20 A. That is correct. If indeed  
21 that was the case I --

22 THE COMMISSIONER: Can I just see that  
23 list again please. Then actually Perreault would  
24 belong in Category 3 then would he not, or in 3, in  
25 No. 3 of Rating 1, would he not? If Perreault were  
receiving digoxin -- no, would he not?





EE2.6

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2 MS. CRONK: Sir, that would depend  
3 on the doctor's judgment as to whether or not the  
4 dose was appropriate. If he didn't know that a dose  
5 had been given he can't therefore at this stage I  
6 suggest make that judgment, unless it is provided to  
him.

7

8 THE COMMISSIONER: You say we have  
9 some record to the effect that Perreault was receiving  
10 digoxin some place other than The Hospital for Sick  
Children?

11

12

MS. CRONK: That is the evidence  
before you, sir.

13

THE COMMISSIONER: Yes. All right.

14

15

16

MS. CRONK: Doctor, I apologize for  
the confusion over that, and I assume more than my  
share of responsibility perhaps, but I think that  
matter has now been clarified.

17

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21

Q. One final question, doctor.  
After you had completed these various coding sheets  
on each of these children, the 36 children now I am  
talking about, did you have any further involvement  
or participation in the preparation of the CDC group  
report?

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A. The only additional thing I  
did for the CDC is they asked me to write a letter to





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them giving them my criteria for the classifications. They also asked me to outline for them my ideas about their various problems of measuring digoxin in various tissues and that was represented by the letter which is enclosed which you have distributed. After that I had no participation in the report.

Q. Do I take it correctly then,

doctor, that you did not play any part or have any involvement in the compilation of the report and the statistics contained in it, save for the coding sheets which you have completed and save for the preparation by you of your letter to Dr. Smith?

A. The only other thing I did I

received a draft of the report to look for errors in the parts that directly pertained to what I had done. I responded to that, and that in terms of dealing with the report itself, my only participation was to check for errors representing my data as I had submitted it to them. I had no part in compiling the data or tabulating it or doing statistics on it or interpreting it.

Q. And before you saw the draft

of the report for that purpose, doctor, did you have any understanding or knowledge as to the use to which the information that you had put together was intended to be put?





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FF  
EMT/cr

2 A. I knew it was going to be  
3 used in some way in an epidemiological study but  
4 beyond that I had no idea how it was going to be used.

5 MS. CRONK: Thank you, Doctor. Thank  
6 you for your patience.

7 Sir, just before I do sit down, amongst  
8 the completed coded sheets that have been distributed  
9 to counsel and marked as an exhibit is one for  
Charlon Gardner.

10 The code number assigned to that  
11 child was 02062 but omitted from the package that is  
12 photocopied for counsel and for the exhibit that has  
13 been marked was a comment page by Dr. Kauffman.  
I would ask that that be admitted now, sir.

14 THE COMMISSIONER: Yes, all right.

15 MS. CRONK: It is being added to her  
16 page.

17 THE COMMISSIONER: Yes. All right.  
18 We will just put it in as page 3.

19 Now the interesting thing is it says  
20 page 4.

21 Miss Cronk, before we go any farther  
22 have we got a page 3? This says page 4.

23 MS. CRONK: This is an amalgam, sir,  
24 of page 3 and 4, all that there is with respect to all

25





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2 of these children.

3

THE COMMISSIONER: All right.

4

MS. CRONK: And, Mr. Commissioner, I

5

will have the Doctor's handwritten notes with  
respect to those categories typed up and I will  
tender them tomorrow morning as an exhibit for  
you, the lists that we have just been reviewing.

6

THE COMMISSIONER: Yes. I wonder if  
we could put some kind of an asterisk with a note  
of whatever information we have.

7

MS. CRONK: Thank you, sir, those  
are all my questions.

8

THE COMMISSIONER: Yes. All right.

9

Mr. Hunt?

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MR. HUNT: No questions.

11

THE COMMISSIONER: Mr. Brown?

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F-2  
EMT/cr

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2 THE COMMISSIONER: Mr. Brown?

3

4 MR. BROWN: I would make a submission  
5 at this time that Mr. Young precede me ---

6

7 THE COMMISSIONER: I am sorry, what?

8

9 MR. BROWN: In view of the fact that  
10 the report was used by the police to assist them in  
11 their investigation in that sense although technically  
12 he may not be a client of the police he was retained  
13 by the police.

14

15 THE COMMISSIONER: What do you say  
16 about that, Mr. Young?

17

18 MR. YOUNG: I don't want to be  
19 difficult, Mr. Commissioner. He is not our witness  
20 but if Mr. Brown - at this point I would be happy  
21 to cross-examine the witness.

22

23 THE COMMISSIONER: All right. Would  
24 you like to proceed? We will probably go on at least  
25 till 5 o'clock. How long do you think you will be?

26

27 MR. HUNT: I would expect about five  
28 minutes.

29

30 THE COMMISSIONER: That really doesn't  
31 get you out of today then.

32

33 MR. BROWN: No.

34

35 THE COMMISSIONER: All right then.

36

37 EXAMINATION BY MR. YOUNG:

38

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Kauffman, ex.  
(Young)

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Q. My name is David Young and  
I am one of the lawyers here on behalf of Metropolitan  
Toronto Police.

5

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8

Doctor, I am going to be referring  
to Exhibit 116 for the short time that I am up here  
and you may want to have that handy. You probably  
do have it. That is the medical record of Justin  
Cook.

9

10

THE COMMISSIONER: I think you have  
it here somewhere.

11

MR. YOUNG: Perhaps Mr. Registrar  
can provide it.

12

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Q. You do have it? All right.

Doctor, at page 25 of that medical  
record there is a note signed by Dr. Jedeikin. That  
note seems to indicate that Baby Cook experienced a  
severe cyanotic spell around 1800 hours on March  
21st, 1981. Do you see that note, Doctor?

A. Yes. 21/3/1820 hours?

Q. That is correct, yes.

Actually it states that the spell  
seemed to be first noticed at 1800 hours.

A. Yes.

Q. And was treated later on.

Doctor, it also appears that Dr.





1  
2-3 2 Jedeikin administered propanolol and that the child  
3 responded well. Would you agree with that?

4 A. He describes it as almost  
5 immediate. Pinking up, murmur increased.

6 Q. Right. And then, Doctor, at  
7 page 29 we have a note that was signed by Nurse Nelles.  
8 Nurse Nelles tells us that at 3:45 a.m. on March 21st  
9 it seemed that this child began to experience some  
10 difficulties. I think we could properly describe this  
11 child as experiencing increasing cyanosis or a cyanotic  
12 spell? Is that accurate, Doctor?

13 A. Is this the note on page 29  
14 dated March 22?

15 Q. That is the one, 1981. She  
16 says here:

17 "Babe settled well after 2:30 feeding.  
18 Rested comfortably until about 3:45  
19 when hands were - "

20 A. Noted to be.

21 Q. "...noted to be more cyanosed.  
22 Vital signs were started when baby  
23 began to have a seizure".

24 21 And then it goes on and on. Would you agree that  
25 22 the baby appeared to be having a blue spell at that  
time, 3:45.





2-4

A. That is what appears, yes.

2

Q. That is what is indicated?

4

A. Yes.

5

Q. Doctor, about half way down

6

page 27 if we could turn to that page there is an  
indication, a note prepared by Dr. Kantak I believe  
that this child was administered more propanolol.

7

Initially the child was given I believe it is 0.4  
millilitres and then a few minutes later approximately  
3:55 the child was given another 0.2 millilitres.

10

11 Is that the way you read that chart,

12

Doctor?

13

A. I am having difficulty reading  
it. I see that - I am not sure. You are talking  
about the second note on the page 27?

15

16

Q. Yes, I am. Almost right in  
the middle of the page there, Doctor.

17

A. It starts out "Called to see  
this baby. Having blue spell".

18

Q. That is correct.

19

A. Now where in that paragraph  
are we?

21

Q. We go down to what might  
be described as the second paragraph.

23

A. Oh, now I see it. "Was given

24

25





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2-5 Inderal .4 millilitres".

3

Q. Right.

4

A. Okay.

5

Q. Then it appears that the child  
did not respond in the same manner as it had at 6  
o'clock. The response does not appear to have been  
one that the doctor was satisfied with and he gave  
an additional 0.2 millilitres a few minutes later.

9

A. Okay.

10

Q. Is that the way you read  
that, Doctor?

11

A. He got some atropine .1  
milligrams.

13

Q. Right. But above that,  
Doctor, it refers to an additional ---

15

A. Oh, another .2 millilitres was  
pushed.

17

Q. Right.

18

A. Okay. Now I see.

19

Q. Then, Doctor, it does not  
appear that the child responded well. I think it  
says responded partially and my friends may be able  
to help me with that.

22

A. That is the way I read it.

23

Q. That is the way I read it as

24

25





1

2 well.

3 Now, Doctor, I should tell you that  
4 for instance Nurse Nelles on page 29 doesn't even  
5 think that the baby responded well. She says again  
6 about half way down just after it says - the word  
7 propanolol is underlined and it says "Another dose  
8 of propanolol was administered at approximately  
3:55".

9 Well, let's start a little earlier,  
10 Doctor, I am sorry. "Propanolol was administered.  
11 Babe remained markedly cyanosed" and then a little  
12 further down she says "Another dose of propanolol  
13 was administered at approximately 3:55. Dr.  
14 Jedeikin called before this last administration of  
propanolol babe's apex then began to dip".

15 A. Yes.

16 Q. "And was approximately 72".

17 Then there is a discussion of other  
18 medication being given to the child, but, Doctor,  
19 would you not agree that there did not appear to be  
20 a similar good response to the administration of  
21 propanolol on this occasion as there had been on the  
earlier occasion at 1800 hours?

22 A. That is the way I understand  
23 these notes, yes.

24

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Q. And, Doctor, we have heard

evidence from Dr. Harry Bain. Do you know Dr. Bain?

A. I just know who he is. I

don't know him personally.

Q. Dr. Bain told us and for the

assistance of my friends it is at Volume 61, page

3664.

Q. Doctor, I would be happy to read you

that evidence but Dr. Bain basically told us that in

light of the earlier good response - he is referring

to the response at 6 o'clock in the evening - it was

rather surprising that the Inderal didn't greatly

assist this child later that evening at 3:45. And his

general impression was that if it worked once it is

likely that it is going to work again.

Q. Would you agree that normally that

is the case, Doctor?

A. Other things being equal I

would agree that would be the expectation.

Q. Now, Doctor, you told us on

a number of occasions that this baby was very, very

likely administered a large dose of digoxin some time

between - well, to be accurate before 3:30 and after

1:30 a.m. on March 21st?

A. Those were my best estimates.





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Q. Doctor, if this baby, Justin

Cook, was already suffering from the effects of digoxin toxicity at 3:45 a.m., would that not explain the very limited or lack of response of the Inderal that was administered at 3:45 and 3:55 a.m. just prior to this child's death?

A. I would have to think about

that a moment.

Q. All right.

A. I think we have to look at

the actions of the two drugs and think what that theoretically could do and think about what kind of heart disease Justin Cook had.

Justin Cook had outflow obstruction to his pulmonary artery, the artery going to his lungs, and that was the reason for his severe cyanosis.

If I recall correctly, and correct me if I am wrong he had a single ventricle with an outflow chamber which represented a rudimentary right ventricle and the reason he was getting cyanotic periodically was that the muscle, heart muscle around the outflow tract of his pulmonary artery would contract and decrease the blood flow to his lungs so he didn't have blood going through to the lungs





1

2 so it could be oxygenated and he became cyanotic.

3 The reason for giving propanolol is  
4 that it tends to relax the heart muscle or reduce  
5 its contractual force. It would relax that constriction  
6 and increase the flow of blood to the lungs and that is  
7 apparently what - they got the response they wanted  
8 and that is a common and appropriate treatment for  
this situation.

2-9

9 Now if in fact he was having cardio-  
10 dynamic effects of digoxin at the time he got that  
11 3:55 dose or thereabouts, the two doses ---

12

Q. 3:45, 3:55.

13

A. 3:45, 3:55. Digoxin

14

increases the contractual force of the heart. If  
indeed he was suffering from the effects of digoxin  
at that point the effect of digoxin in increasing  
the contractual force of the heart could conceivably  
override the relaxing effect of propanolol and block  
its effect in allowing more blood to flow to his  
lungs. That is the best answer I can give you.

15

Q. And that might explain

16

the very limited response of the Inderal?

17

A. It could be an explanation.

18

MR. YOUNG: Thank you very much,

19

Doctor.

20

21





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2 THE COMMISSIONER: Mr. Brown?

3

CROSS-EXAMINATION BY MR. BROWN:

4

Q. Doctor, my name is Brown and  
I represent Nurse Susan Nelles.

5

6 If I might ask you a couple of  
7 questions about a few of the babes, first of all  
Baby Justin Cook.

8

9 I believe it was your evidence  
10 yesterday - well, actually on Monday afternoon and  
11 also yesterday, that in your opinion an overdose of  
12 digoxin was given to the child at some time and I  
13 believe the most likely time frame which you posited  
14 was between 1:30 and 3:30 in the morning. That is  
15 approximately one to three hours before the cardiac  
16 arrest. Am I correct in saying that that is your  
17 best estimate?

18

A. I think that is correct.

19

Q. And indeed if I recall your  
20 testimony you were of the opinion that it would be  
21 unlikely that the digoxin would have been administered  
22 prior to 3:30 in the morning; is that correct?

23

A. I thought that was unlikely,

24

yes.

25

Q. And if I could turn you to

the scoring sheet which you used in the Atlanta - in





2-11

1  
2 the Center for Disease Control Report and I am afraid  
3 I don't have the tab but I am sure it right towards  
4 the end.

5 A. I have my own copy here. I  
6  
7 can turn to it.

8 MR. HUNT: Mr. Commissioner, my friend  
9 said prior to 3:30. I think he may have meant after  
10 3:30.

11 THE COMMISSIONER: I thought it was  
12 between 1:30 and 3:30.

13 MR. BROWN: Yes, Mr. Hunt is quite  
14 correct.

15 Q. The question I was directing  
16 to you in your opinion it was unlikely that the  
17 digoxin would have been administered to Justin Cook  
18 after 3:30. That is less than one hour before the  
19 onset of the cardiorespiratory arrest?

20 A. I think I understood it the  
21 way you meant it, not the way you said it. I meant  
22 to say I thought it was unlikely that it was  
23 administered less than one hour prior to arrest.

24 Q. That is what I meant if I  
25 didn't say it.

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Kauffman, cr.ex.  
(Brown)

G/BM/ak

1  
2 Q. If I could ask you to turn to  
3 the scoring sheet which you used for that child for  
4 the Atlanta Report study. If you could please turn  
5 to the second page of that report, or of the scoring  
6 sheet, there is a right hand margin in which certain  
7 numbers appear. At the bottom of that column appear  
8 at lines indicated as lines 22 and line 28. Do you  
see where those appear, Doctor?

9 A. Yes.

10 Q. My understanding is that you  
11 were asked for a limited number of cases to give an  
12 opinion as to the earliest time a fatal dose might  
13 be given. Do those numbers represent your opinion  
14 in that regard, Doctor?

15 A. I don't recall that they do.  
16 Those are not my handwriting, in fact, I didn't  
17 put numbers in the margin when I scored these. And  
18 I frankly don't recall putting that kind of data  
19 on any of the six sheets. I don't know if it was  
20 originally put on there and then it ended up being  
21 taken off before I did them, I really don't know.

22 Q. The numbers would seem to  
23 suggest that the earliest time would be on March 22nd,  
24 2:45 in the morning, which would certainly fall within  
25 the time frame that you have described here.





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A. I may have done it but I don't have any record that I did it and I don't remember doing it. So, I can't be much more helpful to you. I don't know if they took other information that I gave in my notes and coded that or if I actually did put something down on 6/7. On the copies I was provided after the fact - you see, I did the scoring at the hospital, I left them there and after they had been coded and entered, I assume entered on the computer, I was provided copies after they had put in the coding digits. So, I don't have any record or recollection that I actually went through that exercise in those lines.

Q. So, it may well be figures put in by somebody else with all the information.

A. Could well have been, I just don't know.

Q. Very well. If I could then turn to Baby Janice Estrella.

THE COMMISSIONER: Could it not be based upon what you did say? Obviously your comment "Was likely administered within one hour of the onset of terminal symptoms" and the onset was 3:45. So, they may have put in ---

THE WITNESS: They may have





GG3

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interpreted my comments and coded it in that way,  
yes.

4

5

THE COMMISSIONER: It's sort of a  
bad interpretation.

6

7

THE WITNESS: No, I don't disagree  
with it, I just don't recall doing it.

8

MR. BROWN: Q. So, it is certainly  
within your time frame.

9

A. Yes.

10

11

12

13

Q. If I recall your examination  
yesterday, the one hour time that you said would be  
a minimum, you fixed in relation to the time of  
drawing the sample which was 4:30.

14

A. Yes.

15

Q. So, the latest time which you  
posited would be 3:30 a.m.; the earliest time which  
you posited would be approximately 1:30 a.m. and  
this figure would fall somewhere in the middle.

16

A. Yes.

17

18

Q. So, it is not inconsistent  
with the time window that you presented to us in your  
evidence?

19

A. No.

20

Q. If I might turn then, Doctor,  
to Baby Janice Estrella. We have heard that in your

21

22

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24

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GG4

1  
2 original report to Mr. Wiley, the report dated in  
3 December of 1982, you were of the opinion at that time  
4 that in view of the post mortem readings of 70 and  
5 74 nanograms per milligram in the serum you considered  
6 those readings to be excessively high and, coupled  
7 with the low tissue reading, you considered those  
8 readings would be consistent with a large dose of  
9 digoxin administered shortly prior to death.

10 I would refer you to page 7 of your  
11 letter and in the second full paragraph, last half  
12 of the paragraph I believe deals with that initial  
opinion which you have.

13 A. Yes. I have it here.

14 Q. My recitation I believe of  
15 your evidence was correct, at that time you were of  
16 the opinion that a significant dose of digoxin had  
17 been given to that child shortly before her death?

18 A. That is correct.

19 Q. And then you were subsequently  
20 advised of the source of that sample, that the  
21 source of that sample was taken from the pelvic  
22 cavity of the child and I understand you were also  
23 advised of the results of a gutter blood study that  
24 had been conducted by the Hospital for Sick Children  
25 and Mr. Cimbura, the Centre of Forensic Sciences,





Kauffman, cr.ex.  
(Brown)

GG5

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2 is that correct?

3

A. That is correct.

4

Q. And on the basis of that  
5 new information I believe you changed your opinion  
6 and the evidence which you gave yesterday, and this  
7 can be found at Volume 71, page 5729, was that in  
view of the new information - well, I can simply  
8 read it to you.

9

A. Do I get a chance to look back  
10 at my previous days of testimony?

11

THE COMMISSIONER: Yes, yes, you do.  
I think Mr. Young is going to come to your assistance.

12

THE WITNESS: Thank you.

13

MR. YOUNG: You're welcome.

14

THE WITNESS: Which page are you on?

15

MR. BROWN: 5728.

16

THE COMMISSIONER: I guess you can  
read it just in case people don't have it.

17

MR. BROWN: Q. I will be starting  
18 at line 7, Doctor, the question starts there:

19

Q. And we know, Doctor, as you  
learned, that the Estrella level of  
20 72 nanograms on the post mortem specimen  
21 was obtained from a gutter blood or  
22 pelvic cavity specimen. In light of  
23

24

25





GG6

1  
2 "your knowledge of this case, Doctor,  
3 and the results of the gutter blood  
4 study which was provided to you, would  
5 you, as a pharmacologist, dismiss the  
6 72 nanograms level as meaningless in  
7 light of the source and the manner of  
its sampling?"  
8

9 And your response is on page 5729:

10 "A. I wouldn't dismiss it, but  
11 I have to have much less confidence in  
12 it. The problem this poses is that  
13 this was the one piece of information  
14 that really made the difference in  
15 making that judgment in this case  
16 and losing confidence in that number  
17 in this particular case really left  
very little else to deal with."

18 And I believe on the basis of that  
19 information you were given you wrote a second report  
20 to Mr. Wiley. The letter was dated January 17, 1983.  
21 If I might refer you to the second page of that  
letter, the last paragraph:

22 "The estimate of possible doses of  
23 digoxin outlined in paragraph 4 under  
'Summary and Evaluation of Janice

24  
25





Kauffman, cr.ex.  
(Brown)

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GG7

"'Estrella' is only valid if one assumes that the level of 70 nanograms per millilitre measured in 'gutter blood' reflects the actual post mortem serum concentration of digoxin. Since the measurement of digoxin in the post mortem blood was critical to making a judgment in the Estrella Case, it is my opinion that this case is open to serious challenge and in itself does not provide a strong basis for a theory of homicide."

And it is my understanding, Doctor, that that is your opinion today, is that correct?

A. That is correct regarding that specific case.

Q. Regarding simply the case of Janice Estrella.

A. Right.

Q. Indeed, I suggest, Doctor, that it was on the basis of that new information on the significance of the post mortem sample that you changed the scoring of Janice Estrella in the Atlanta Report. If you wish to refer to the scoring sheet of Janice Estrella, which is at Tab 25. On





Kauffman, cr.ex.  
(Brown)

GG8

1  
2 the front page of that scoring sheet there is a  
3 notation that "Dr. Kauffman called the change 5 to 2"  
4 and I believe Miss Cronk asked you this before you  
5 originally scored the child as a 5, but am I correct  
6 in saying that in view of the new information on the  
7 post mortem blood you changed it to a 2?

8 A. That is correct.

9 Q. If, Doctor, the post mortem  
10 levels of 70 and 74 which were obtained from the  
11 pelvic cavity are valid samples and accurately  
12 represent the amount of digoxin in the post mortem  
13 blood of Baby Janice Estrella, I believe that on that  
14 basis you attempted to calculate the dose, the time  
15 and the mode of administration for that child, and  
16 if I could refer you to page 7 of the first letter  
17 that you wrote to Mr. Wiley, the second to last  
18 paragraph on that page, the last two sentences, I  
19 believe you first stated that:

20 "It is unlikely that the dose was  
21 administered orally since this  
22 infant was quite ill and was receiving  
23 oral fluids by nasogastric tube."

24 I take it, Doctor, that that is also  
25 the opinion which you presently hold?

A. Yes, I agree with that.





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Q. And the next sentence:

"It is also somewhat unlikely that the dose was diluted in the bottle of intravenous fluid or buretrol since the acute onset of critical symptoms and the relatively low myocardial levels are not particularly consistent with a prolonged infusion."

And I would take it, Doctor, that

that is also your present opinion today?

A. I still agree with that.

-

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-





Kauffman  
cr.ex. (Brown)

30nov83  
GG2.1  
BMcra

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2 Q. And the reason, Doctor, that  
3 you would rule out the intravenous bag or buretrol  
4 as a potential mode of information I suggest is two-  
5 fold: first of all, the acute onset of the critical  
6 symptoms demonstrated by this child on the morning of  
7 her death.

8 A. That was part of it.

9 Q. That was part of it. I take  
10 it the critical symptoms in this child started  
11 approximately at 2:40 a.m. in the morning, and if I  
12 might refer you back to the paragraph at the top of  
13 page 7, the last sentence:

14 "At 2:40 on 11/1/81 she was noted to  
15 be gasping..."

16 Were those the terminal events that  
17 you were referring to as being acute?

18 A. I'm sorry, I lost you. She is  
19 where?

20 Q. I'm sorry?

21 A. Oh, at 2:40 on 11/1 she was  
22 noted to be gasping?

23 Q. "...with rapidly increasing  
24 respiratory rate."

25 A. Yes. I think that that is  
what I was identifying as her terminal event.





Kauffman  
cr.ex. (Brown)

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Q. So that in your opinion, or  
the basis of your opinion was that the acute critical  
symptoms or the acute onset of critical symptoms  
commenced somewhere around 2:40 that morning?

A. In that neighbourhood, as near  
as I could tell from the chart.

Q. And the second reason that you  
suggested or came to the opinion that the administration  
by the IV bag or buretrol was unlikely was the relative-  
ly low myocardial levels found in this child, is that  
correct?

A. Yes, although they were fixed  
tissues but they were still quite low even for fixed  
tissues I thought.

Q. Doctor, if a dose of digoxin  
was placed in the buretrol of an intravenous line  
and then allowed to infuse into the line within a  
period of, let us say, 30 minutes, when would you  
expect the onset of the critical symptoms to occur?

A. Well, that depends on a number  
of variables and this gets into a complex area that I  
don't think I have discussed before. I can't give you  
a simple answer. It depends, one, on the volume in  
the buretrol into which the dose was placed, whether  
it was 5 cc. or 100 cc. or somewhere in between because





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2 GG2.3 that defines the amount of fluid into which it  
3 diffuses and has to run in before it is all into the  
4 patient; it depends on the length of the IV tubing  
5 at that point in time because that's the dead space  
6 through which it has to go; it depends on whether the  
7 IV tubing was hanging below the crib at some point  
8 so that the drug, because of a difference of specific  
9 gravity might layer out in the depended part of the  
10 tubing; it depends on the intravenous flow rate  
11 because that determines the length of time it takes  
12 the first part of the drug to arrive at the patient  
13 and it also determines the length of time it takes  
14 for the entire dose to be infused into the patient.

15 There are data that I don't have with  
16 me which have worked out these kinds of fluid  
17 dynamics. So, there are variables here that can make  
18 an enormous difference; in other words, if the dose  
19 was placed in the buretrol in a relatively large  
20 volume, I'm talking something a little more than 40  
21 millilitres, and the IV flow rate was 3 to 10 milli-  
22 litres per hour, which wouldn't be improbable for  
23 this kind of a patient, I don't know what it was  
24 actually, it might take 6 to 8 hours for 100 per cent  
25 of that dose to actually be infused into the patient.

The first bit of digoxin would





Kauffman  
cr.ex. (Brown)

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GG2.4 2 reach the patient in, if the dead space in the tubing  
3 was 15 to 18 millilitres, which isn't unusual,  
4 depending on the length of the extension tubing, the  
5 first digoxin would reach her at a flow rate of 10  
6 in something over 1 to 2 hours and then dribble  
in over the following hours.

7 Q. Well if I could perhaps put  
8 a couple of hypotheticals to you. If you could assume  
9 that the digoxin was diluted in no more than 10 cc.  
10 of the IV fluid and if you would assume that that  
11 amount of material was infused into the child over a  
12 period of no more than 30 to 40 minutes, and let us  
13 assume that the IV line runs relatively straight to  
14 the child and there is not much of a dip, on that  
15 basis would you be able to give an opinion as to  
16 when you would expect to see the onset of the critical  
symptoms in that child?

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A. You mean the entire 10 million litres would go without any other fluid being added to the buretrol at all, would be allowed to infuse into the patient?

Q. Yes.

A. That is very hypothetical because that would allow air into the line behind the fluid and that usually is done, but I will deal with that.

THE COMMISSIONER: Before you deal with it though are these facts upon which we have had evidence?

MR. BROWN: No, there has been no evidence on these facts.

THE COMMISSIONER: Are you just - you don't need to answer this, but are you picking these facts out of the air or do you have some knowledge of them? Because --

MR. BROWN: They are of some relevance.

THE COMMISSIONER: They certainly have relevance if they happen to be true, but do you know whether they are or not, does it assist us?

MR. BROWN: I think the facts I am putting to him are reasonable and may well come out at some later time.





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2 THE COMMISSIONER: I see, all right.

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4 THE WITNESS: I can't tell you exactly  
5 but I will do the best I can, can you give me dead  
6 space for the tubing and flow rate?

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MS. BROWN: Q. I am asking you to

assume that the quantity that was in the buretrol was  
infused at an even rate over a period of 30 to 40  
minutes, what that comes down to in terms of cc's per  
minute, it is obviously greater than 10 cc's, perhaps  
between 15 and 20 cc's per hour.

A. Okay. I suspect that once

that dose was in during that time that you could see  
critical symptoms, possibly see critical symptoms I  
would guess anywhere from 15, 20, 30 minutes up to  
maybe an hour or more. It is extremely variable when  
you read the literature about the onset of symptoms  
from known intoxication, the onset is somewhat  
variable.

Q. You would expect nonetheless  
to see the onset of critical symptoms within a -  
within a relatively short period of time?

A. A relatively short time once  
the dose was all in.

Q. If I may then turn, Doctor, to  
Baby Kevin Pacsai. I believe it was your evidence





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2 this morning, although in this respect I am only  
3 relying on my notes, that you had difficulty in  
4 determining whether this child received a dose of  
5 digoxin orally or parenterally. But if I may, if I  
6 could put it this high it was probably your better  
7 view that he received an oral dose of digoxin, would  
that be a fair summary?

8

A. I think that is as I recall a  
fair summary of what I said.

9

Q. And if I also recall you said  
10 if he received an oral dose it would be most likely  
11 that that dose was administered in a very broad time  
12 frame between six to twelve hours before the onset  
13 of the critical conditions, is that a correct summary  
14 of what you said?

15

A. A rather broad time frame, yes,  
16 long enough for distribution but I doubt if it was  
17 before 12 hours because we have normal potassium, and  
18 he looked okay prior to that, the twelve hours before-  
hand.

19

THE COMMISSIONER: It was greater  
20 than twelve hours?

21

THE WITNESS: Greater than twelve  
22 hours, I doubt if it was greater than twelve hours.

23

MR. OLAH: Just briefly, is that twelve

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2 hours before death or onset of symptoms?

3 MR. BROWN: Well, I am just coming  
4 to that, Mr. Commissioner.

5 THE COMMISSIONER: Yes, all right.

6 MR. BROWN: Q. If I recall, in response  
7 to a similar question that Miss Cronk posed to you  
8 this morning, you stated that the benchmark that you  
9 were using was the onset of critical symptoms which  
10 occurred somewhere in the neighbourhood of 3:30 or  
11 3:45 on the morning of this child's death, is that  
12 correct?

13 A. That is when I got a clue from  
14 the chart that something had changed, yes.

15 Q. So, applying the time window  
16 that you posited to that benchmark, would I be fair in  
17 saying that it is your opinion that the oral dose of  
18 digoxin could have been administered as early as 3 or 4  
19 p.m. on the previous afternoon, March 11th, that is  
20 12 hours before 3:30, the morning of March 12th?

21 A. I think I postulated that it  
22 could have possibly been given on the schedule dosing  
23 time of 2100, or could have been given at both  
24 scheduled times, the time before that and at 2100.

25 THE COMMISSIONER: I thought we  
26 decided there wasn't --





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2 THE WITNESS: That is where I was  
3 confused.

4 THE COMMISSIONER: You said there  
5 wasn't one at 9 o'clock.

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7 THE WITNESS: When I wrote my report  
8 I was under the impression that he had received two  
9 doses, and today looking at their medication sheet I  
10 notice that it looked like it may have been only one  
11 dose. I think that that dose could be included in  
12 the outside limits, that is that time.

10

11 MR. BROWN: Q. The first dose that  
12 you thought he had been given?

13

A. Was 2100.

14

15 Q. The 2100 on the evening of  
16 March the 11th, which would be approximately six hours  
17 prior to the onset of the critical symptoms at about  
18 3:30, 3:45 the following morning?

19

A. Right.

20

Q. So that dose could be included?

21

A. It could be.

22

23 Q. And from what you were saying,  
24 one could also include, could you not, the period of  
25 time six hours prior to the administration of that  
dose, that is approximately 3, 3:30 in the afternoon  
up until 9 o'clock in the evening, would that be  
correct?

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A. I would have to - I think it is unlikely, although he could have, I think it is unlikely that he received as much before that potassium level of 3.9 was drawn and I can't remember the exact time of that, before I answer you specifically as to time frame.

MR. OLAH: I think that was 1745 in the afternoon.

THE WITNESS: That would have been 5:45 in real time.

Q. So it would be unlikely in your opinion that the dose was administered orally prior to 5:30 the previous afternoon.

A. Yes, I think, yes, I think that's fair.

Q. But that some time between 5:30 that afternoon and the onset of the critical events at 3:30 the following morning, would be a period of time in which oral administration could be possible to achieve those levels?

A. I think I agree that those are the outside limits of the range that I could postulate. I felt from looking at the chart that things really started changing at 3:35 point when the baby was described as being very different. Reading other





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(Brown)

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2 cases reported in the literature with mainly  
3 intoxication, those kinds of time frames after an  
4 oral dose have been described in that ball park.

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3 Q. If I might refer you to page 8  
4 of your letter to Mr. Wiley, the first letter. You  
5 also entertained the possibility, and I am reading  
6 the last sentence of the last full paragraph, that  
7 this child could have received an overdose of digoxin  
8 through the intravenous route some three to six hours  
9 prior to the onset of the critical symptoms, that is  
another opinion that you hold, is that not right?

10 A. That was another guestimate,  
11 and I thought it was a reasonable possibility. I  
12 really couldn't say whether or not it was intravenously  
13 or oral, but I thought it was a little more probable  
orally but I wouldn't argue one way or the other.

14 Q. Two sentences above that on  
15 the same page of the report, or three sentences it  
starts:

16 "The excessive dose could have been  
17 given either orally or parenterally.  
18 For example, an excessive dose could  
19 have been given orally at the scheduled  
20 dosing time of 2100 hours 11/3/81 and  
21 result in the clinical course which  
ensued."

22 And I believe this morning Miss Cronk  
23 took you through an exercise and we determined that

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25





Kauffman, cr.ex.  
(Brown)

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2 the prescribed dose at that time was .02 milligrams  
3 of digoxin; do you recall that figure?

4 A. Was it .02 or .0-- .02 you are  
5 correct, you are correct.

6 Q. And I believe you calculated  
7 that that quantity translated into a volume of .4  
8 millilitres of the digoxin elixir.

9 A. Yes, I agree.

10 Q. And Miss Cronk then took you  
11 through the exercise which you performed on the bottom  
12 of page 8 and the top of page 9 of your report in  
13 attempting to calculate a minimum oral dose of digoxin  
14 to produce the concentrations found in the serum and  
15 the tissues, and as a result of that exercise you  
16 posited a minimum oral dose of .7 milligrams of the  
17 digoxin, that is the accurate figure?

18 A. Yes.

19 Q. Which would be contained in  
20 14 millilitres of the digoxin elixir?

21 A. Correct.

22 Q. And the minimum dose which  
23 you postulated would exceed the prescribed dose by  
24 approximately 35 times, is that correct?

25 A. I think that is correct.

Q. Therefore, the dose would be





Kauffman, cr.ex.  
(Brown)

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2 significantly larger in volume. I believe you said  
3 that it might well require a different container or  
4 syringe to be administered than with the prescribed  
5 dose, is that correct?

6 A. That is correct.

7 Q. Doctor, are you familiar with  
8 the procedures used at the Hospital for Sick Children  
9 to administer digoxin to children?

10 A. No, I am not.

11 Q. Well, if I could perhaps put  
12 to you 4 assumptions which we have to test at some  
13 later time. If you would assume with me that in  
14 order to give a dose of digoxin, a nurse first  
15 consults a medication card which is kept for each  
16 child, and upon that card is written the dose and  
17 the time of administration for that child.

18 If you would then assume as the second  
19 feature, that having read that card the nurse would  
20 then take the drug and draw up the appropriate amount  
21 of digoxin.

22 The third step that the nurse who  
23 drew up the medication would then take that syringe  
24 to another nurse along with the medication card,  
25 show the card and the syringe to the other nurse and  
ask her to confirm that the quantity that is drawn





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2 up in fact reflects the quantity prescribed.

3 If you would assume for me that those  
4 are the steps involved at the Hospital for Sick  
5 Children to administer digoxin to children, would  
6 you agree with me that if a dose which exceeds the  
7 prescribed dose by 35 times was shown to the nurse  
8 who was to check the dose that that huge increase  
9 in volume would be apparent to the second nurse.

10 A. I think it would be.

11 Q. And indeed, if because of  
12 that large volume a different container or syringe  
13 had to be used in order to administer that volume,  
14 the second nurse that checked the syringe would  
15 probably notice that there was in fact a different  
16 vehicle being used, would you agree with me that that  
17 would be likely?

18 A. I certainly would.

19 Q. And if you assume with me,  
20 Doctor, that that in fact was the procedure used  
21 when the dose prescribed to be administered at  
22 9 o'clock on the evening of March the 11th to Kevin  
23 Pacsai, and those four steps were used, would that  
24 not in your mind decrease the likelihood that the  
25 dose administered at that time exceed the prescribed  
dose by 35 times?





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2 A. I think the only way that could  
3 happen would be if the procedures were grossly violated.

4 Q. And if the procedures were not  
5 grossly violated, but in fact were conformed with,  
6 that would reduce, in your opinion would it not,  
7 the likelihood of an excessive dose being administered  
8 at that time?

9 A. Yes, I think so.

10 MR. BROWN: Thank you, Doctor.

11 THE COMMISSIONER: I think we will  
12 just take a poll. Mr. Strathy, how long do you think  
13 you are going to be?

14 MR. STRATHY: Probably an hour and  
15 a half to two hours, Mr. Commissioner.

16 THE COMMISSIONER: Miss Thomson?

17 MS. THOMSON: Mr. Scott will be  
18 conducting the cross-examination and I think he will  
19 be about an hour to an hour and a half.

20 THE COMMISSIONER: An hour to an  
21 hour and a half?

22 MS. THOMSON: Yes, sir.

23 THE COMMISSIONER: Mr. Ortved.

24 MR. ORTVED: I think about half an  
25 hour, Mr. Chairman.

26 THE COMMISSIONER: Miss Symes?





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Kauffman

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MS. SYMES: Depending upon the  
questions asked by Mr. Strathy and Mr. Scott I would  
say an hour and a half.

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MS. JACKMAN: Depending on the  
questions that go before I would say half an hour to  
an hour.

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MR. OLAH: I would be probably about half an hour, Mr. Commissioner, but have difficulty on Friday. I would not be most likely able to attend on Friday and I would be most grateful, sir, if you could accommodate me by --

THE COMMISSIONER: Well perhaps you could arrange with someone. I don't know why I should pick on her but Miss Symes would let you in ahead of her. Up the queue somewhere.

I was just thinking because this looks like tomorrow before we get to the parents. Are any of the parents intending to be longer than an hour? I would like to get through everybody except the parents tomorrow and of course if we reach the parents we might get on to them as well.

Are any of the parents in trouble on Friday?

MR. TOBIAS: Yes, Mr. Commissioner, I will be required to be in another court Friday morning but I could probably be here by 11:30 at the latest.

THE COMMISSIONER: Well that looks to me as though that would be all right but you might also see perhaps if you may want to take over from somebody as well tomorrow.





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2 Well, I think I would like to start --  
3 I know it is against the principles but I would like  
4 to start early tomorrow. It is the only real chance  
5 we have and I would like to sit until we are through  
6 everybody but the parents if we can tomorrow and I  
7 think ensure that Dr. Kauffman can first of all  
8 leave on Friday afternoon and secondly if he does  
9 come back to Toronto it will be for other purposes  
than ours. So 9:30, does it shock anybody?

10 Well I think we will make it 9:30  
11 then tomorrow morning and you will be here, Mr.  
12 Strathy, that is the main thing, and is it all right  
13 with you, Dr. Kauffman, early morning?

14 THE WITNESS: I usually start my  
15 day much earlier than that.

16 THE COMMISSIONER: We have found that  
17 doctors do start earlier and quit earlier.

18 THE WITNESS: I would be most grate-  
19 ful if I could eventually use my return ticket to  
20 Detroit.

21 THE COMMISSIONER: What time is that  
22 on Friday?

23 MS. CRONK: It is being negotiated,  
24 sir.

25 THE COMMISSIONER: Well let's start  
at 9:30 tomorrow and see how we are making out by noon.

--- whereupon the hearing was adjourned at 4:45 p.m.  
until Thursday, the 1st day of December 1983 at  
9:30 a.m.





